California Biomonitoring Needs Assessment

Report to the Advisory Committee
October 28, 2002

A Project of the California Department of Health Services and Impact Assessment, Inc.

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Executive Summary
California Biomonitoring Needs Assessment

In October of 2001 California was one of 33 States to receive funds from the Centers for Disease Control and Prevention (CDC) to support a biomonitoring planning initiative. As the first phase of the project, a needs assessment was conducted to identify critical issues for California. The Biomonitoring Planning Project Needs Assessment was conducted from April to August 2002. Our planning process emphasizes the pivotal role of the needs assessment in guiding the selection of biomonitoring projects to plan and propose to CDC for implementation funding. The assessment identified critical needs for biomonitoring by including a broad range of public and private stakeholders with special emphasis on evaluating exposures to toxic substances in populations at higher risk. The assessment also identified potential research collaborators for the next phase of the project planning. This needs assessment had four components:

1. A survey of local health and environmental health officials and non-governmental and tribal organizations for input on health hazards and health effects of concern, as well as populations at higher risk: referred to in this summary as the Community Survey;
2. A survey of environmental health researchers to identify current biomonitoring research issues and potential study collaborators: referred to as the Researcher Survey;
3. An inventory of existing state laboratory capacity to provide a baseline for laboratory expansion, document special expertise, and identify sophisticated instrumentation; referred to as the Laboratory Inventory; and
4. A review of selected environmental health reports to provide an overall perspective on biomonitoring in support of environmental health.

Findings

Toxic Substances of Concern

- Based on responses from the Community Survey, pesticides are the substances of most concern. Other leading substances are heavy metals (mercury, lead and arsenic in particular), environmental tobacco smoke, persistent organochlorines, and volatile organic compounds.

- The Researcher Survey showed that 12 of 33 recent and ongoing studies in California focus on pesticides as chemicals of concern, while six focus on metals. Air contaminants are the focus of six exposure studies and water contaminants are examined in three studies.

Health Effects

- Health effects of most concern to Community Survey respondents are cancer and respiratory disorders. In addition, about a third of all respondents are concerned about developmental disorders. Half of responding local health and environmental health officials are concerned with cardiovascular disease, and a third with endocrine disorders.

- Among researcher respondents, ten of their studies explore reproductive outcomes, including but not limited to birth defects, in relation to environmental exposures. Six studies look at cancer and its possible association with various chemicals. Another six are focused on respiratory effects, mainly asthma. Neurodevelopmental disabilities, including autism, are the focus of four studies, and others are concerned neurological diseases (including Parkinson's disease), acute illness due to pesticides, and cardiovascular disease.

Populations at Increased Risk of Exposure

- Among the populations studied in the 33 research projects, eleven are children and six are women of reproductive age. Three are workers and their occupational exposures. Three studies focus on low income and racial groups, and seven on specific geographic regions.

  Community Survey respondents listed some specific locations and populations with associated exposure. Most populations, however, were defined less often with regard to a geographic location than to an activity (such as subsistence fishing in contaminated waterways) or proximity to a generic source of exposure (such as a transit corridor).

Laboratory Inventory

- The Laboratory Inventory revealed a broad range of biomonitoring laboratory methods and chemical testing in the state. Among the respondents, a commercial laboratory had the most methods and broadest capability for biological monitoring. Most of its work is related to occupational testing and some of its methods would need to be made more sensitive for environmental studies such as those conducted as part of the NHANES survey. Other laboratories with considerable expertise in biomonitoring were the California Department of Health Services Chemical Agents Biomonitoring Unit laboratory, which has tested for many pesticides, and the California Department of Toxic Substances Control's Hazardous Materials Laboratory, which has special expertise in analyzing for dioxins, furans and other persistent organic compounds.

Review of Selected Reports

- Several of the reviewed reports emphasize the need for better interagency collaboration to strengthen environmental public health efforts. Taken together, the reports highlight populations, substances, sources of exposure, and health outcomes of particular concern. Among these are widespread exposure to air pollutants and pesticides, reproductive and developmental toxicants, and endocrine-disrupting chemicals. The latter are of growing concern for their possible effect on children and the fetus, and their possible association with breast and other cancers. The reports point especially to children as a vulnerable population that has not received adequate attention in regards to environmental studies and interventions.

Conclusion

There is dramatic agreement among California's local public and environmental health officials and non-governmental and tribal organizations as to the most important toxic substances and health effects. This agreement is echoed by environmental health researchers in the focus of their current studies. The chemical groups of highest concern -- pesticides and heavy metals --can be measured in human samples using methods, expertise and instrumentation that are present in the State laboratories. However, present testing capacity and sample throughput (the number of samples that can be analyzed in a period of time) for these chemicals is very limited.

Other environmental chemicals of concern to those surveyed are environmental tobacco smoke, persistent organochlorines, and volatile organic compounds. Laboratory capability either exists or could be developed in the state's laboratory network to measure these substances. The primary laboratory challenge is not so much in developing capability as in improving sample throughput in order to meet the needs of population-based biomonitoring.

The Needs Assessment has identified the toxic substances of concern to Californians, potential collaborators for biomonitoring projects to plan, and the existing laboratory expertise for biomonitoring within the state laboratory network.

The next phase of the project will focus on the process for selection of biomonitoring projects to plan. A formal, but flexible structure is proposed that will bring to bear both scientific criteria and decision maker values, take into account the Needs Assessment results, and help us select projects that have the greatest chance of succeeding.

Introduction

Organization of this report

This report summarizes the California Biomonitoring Planning Project Needs Assessment. The report is organized into five sections and several appendices. Sections 1 through 3 present results of three surveys (county health and environmental health officials, non-governmental and tribal organizations, and researchers) to identify priority environmental health concerns in California and potential research partners for subsequent phases of the project. Section 4 contains a review of major reports that provide perspective on environmental health and biomonitoring. These four sections summarize the findings of the Needs Assessment. Section 5 describes a decision making process to guide the selection of biomonitoring projects to include in the Biomonitoring Plan. Appendices I though VII contain the survey instruments and lists of respondents, and lists of potentially exposed populations, current environmental health research, and banked human specimens in California.

The Biomonitoring Planning Project Advisory Committee reviewed this report in October 2002, resulting in some changes to the document. At the Committee's request, the Researcher Surveys will be reviewed for both emerging issues and issues of concern, which will be compared with those reported in the survey of local and tribal officials and non-governmental organizations. Staff will also follow leads suggested by the Committee to identify and survey researchers who may have been missed by the Researcher Survey. These new analyses and survey results are forthcoming and not included here.

What is biomonitoring?

Biomonitoring, for the purposes of this project, is the assessment of exposure to toxic substances in people by the laboratory measurement of these substances (or their metabolites) in human specimens, such as blood, urine, or saliva. It can be used to establish the body burden or internal dose of specific environmental contaminants through all routes of exposure.

Biomonitoring information can assist in linking environmental exposures and pollution-related disease. Population-based biomonitoring, in combination with environmental monitoring (e.g. of air, dust, water, food, and soil), can provide detailed information about differences in exposures across geography, race/ethnicity, and socio-economic status. Biological monitoring can also illuminate the relationships between genetic predispositions or sensitivities and disease outcomes. Once associations are known, biological monitoring information may help explain differences in rates of birth defects, asthma, cancer, and other diseases in relation to environmental causation.

Biomonitoring is used in public health practice to:

1. Measure the prevalence of elevated levels of toxic substances in a population (e.g. the prevalence of blood lead levels greater than a certain threshold in children living in a inner city environment);
2. Determine levels of exposure in population groups who may be at increased risk of exposure;
3. Provide levels of human exposure in studies examining the relationship between exposure to toxic substances and adverse health effects;
4. Determine whether levels of toxic substances are higher in vulnerable population groups such as children, the elderly, or women of childbearing age than in the general population;
5. Track over time, trends in the levels of exposure of a population group to specific toxic substances (e.g. levels of exposure to mercury in a population who consume fish as a major portion of their diet);
6. Assure the effectiveness of public health efforts to reduce exposure of specific populations to toxic substances.

Background of the Planning Project

In October of 2001, California was one of 33 States to receive funds from the CDC to support a biomonitoring planning initiative. The goal of the initiative is to a) assess the need for biomonitoring to support public health within the State, with special emphasis on evaluating exposures in groups that may be at increased risk, b) develop a plan to expand current laboratory biomonitoring methods to meet the identified needs and c) identify and plan specific public health biomonitoring projects that could be implemented with additional funding from CDC and other sources. California will submit its final biomonitoring plan to CDC in June 2003 to apply for implementation funds. CDC expects to make approximately 5 awards to state public health laboratories at $1,000,000 per laboratory, per year, for up to five years.

To receive CDC implementation funds, State labs must partner with non-laboratory research collaborators to use biomonitoring for improved public health exposure assessment. The majority of implementation funds will be dedicated to expanding existing laboratory capacity to test for toxic substances in human samples. Thus, non-laboratory collaborators need to have an established infrastructure to support research efforts or be able to create such infrastructure through separate funding.

The overall goal of the California Department of Health Services Biomonitoring Planning Project is to develop a plan to expand laboratory support for public health biomonitoring in the state, in order to provide better information about Californians' exposures to toxic substances and thus helps prevent environmentally-caused disease. The planning process integrates multiple perspectives on California's environmental and occupational health concerns through collaboration with public, private, academic and community-based partners.

The planning process consists of three phases for expanded biomonitoring within the State's laboratory network. They are:

1. A Needs Assessment of toxic substances, health effects and populations of concern;
2. The selection of biomonitoring projects to plan;

The development of a Biomonitoring Implementation Plan.

The following sections summarize findings from the Needs Assessment, and describe a proposed framework for the selection of biomonitoring projects to plan.

Section 1.
Summary of Surveys of Local Health and Environmental Health Officials and Non-governmental Organizations and Tribal Agencies

Introduction

Local health and environmental health officials, Tribal environmental officials, and organizations that focus on environmental health have a tremendous amount of knowledge about potentially toxic exposures in California and related community concerns. Many are active in state, national, and international professional and policy organizations that address these issues. To tap into this rich source of experience and ideas, we conducted two statewide surveys. We had four goals, within the overarching goal of informing our Needs Assessment:

- Inform people of the Biomonitoring Planning Project
- Solicit their input
- Learn their priorities concerning biomonitoring
- Identify potentially exposed populations to consider for inclusion in a research project
- Guide decision making on which biomonitoring projects to plan

We sought the following information in our surveys:

- Toxic substances of concern
- Health conditions of concern
- Exposure sources of concern
- Emerging environmental health issues
- Local experience with biomonitoring
- Populations at particular risk of past or present exposure
- General reactions to the Project.

Methodology

To identify priority toxic substances and health conditions, the surveys included lists from which respondents were asked to check items of concern, prioritizing their top three. Respondents could add additional items to the survey lists. These lists were compiled from several of the relevant state and national reports summarized in Section 4 and Appendix VII [1], page 76, and modified by the Project's Working Group and

[1] Reports included *National Report on Human Exposure to Environmental* Chemicals (CDC, March 2001); *Toxic Chemicals: Long Term Coordinated Strategy Needed to Measure Exposures in Humans* (US GAO, May 2000); *America's Environmental Health Gap* (Pew Environmental Health Commission, September 2000); *California*

Advisory Committee to combine closely related items and for relevance to California.[2] The draft surveys were field tested with non-governmental organizations and with local health and environmental health officials and revised accordingly. The survey instrument appears in Appendix I, page 42.

Slightly different surveys were sent to the local officials, and to the non-governmental organizations (NGOs) and Tribal organizations (TOs), and the responses were analyzed separately. Local officials are responsible for the entire population within their jurisdiction and for a broad range of health and environmental health matters under state and federal law, local ordinances, and public health practice. In addition, we know the number of local officials and the percent of the state's population that each represents. On the other hand, NGOs with an interest in environmental health may be concerned with one, a few or many issues and represent a population whose demographics are unknown, and we did not have access to a list of all such organizations. Tribal and Non Governmental Organizations received the same survey.

We sent the survey by e-mail to each local Health Officer and local Director of Environmental Health in California, representing all 58 counties and 4 cities.[3] We also surveyed NGOs and Tribal Environmental Managers by e-mail, and estimate that we reached approximately 300.[4] An effort was made to increase participation through follow-up calls and e-mail reminder notes.

The surveys were designed to provide qualitative rather than quantitative information, though some quantitative information could be drawn by tabulating responses.

Results

Who responded to the survey?

Local officials: Thirty-two counties and two cities (out of 58 counties and 4 cities) responded, representing 82% of California's population. Jurisdictions we did not hear from are primarily rural counties in the Sierras and the north part of the state (above Sacramento), but also included several Bay Area and Central Valley counties and two cities. See Appendix II on page 48 for a list of respondents.

Comparative Risk Project Report (OEHHA, Cal/EPA 1994); and *Environmental Protection Indicators for California* (Cal/EPA, October 2001)

[2] We thank the Survey Research Center, University of California, Berkeley, for valuable advice on instrument design.

[3] We are indebted to the California Conference of Directors of Environmental Health for help in soliciting field-testers and for sending the survey and follow-up notes to their members, to the California Conference of Local Health Officials for use of their membership contact list, and to the Presidents of each organization, Keith Winkler, REHS and Dr. Poki Namkung, for co-signing the cover letter.

[4] We are grateful to Commonweal, the Breast Cancer Fund, Pesticide Action Network-North America, the National Environmental Trust, the South Coast Air Quality Management District, CalEPA, Californians for Pesticide Reform, and the Center for Environmental Health for generously providing us e-mail addresses or forwarding the survey to their list on our behalf, and to Advisory Committee member Mr. Eddie Phillips for distributing the survey to Tribal Environmental Managers.

Ten local officials reported biomonitoring and mentioned lead poisoning tests; one noted carbon monoxide screening, and one occupational monitoring.

Local officials listed a wide variety of environmental health concerns, in response to an open-ended question. Responses to more detailed questions are described below.

Tribal and non-governmental organizations: Ten TOs and 38 NGOs replied. All but one of the TOs are located north of the San Francisco Bay Area. Of the 38 non-governmental organizations, 10 are local, 9 regional, 8 statewide, and 11 national. Of the 28 whose organizations are not "local," 11 indicated that they spoke for their entire organization and 17 only for their local branch. Most of the organizations' offices are located in the Bay Area (25); 13 are in Southern California (including San Luis Obispo) and 3 are in or north of Sacramento. A list of respondents may be found in Appendix II, page 48.

Thirty-six of the TOs and NGOs represent the concerns of particular groups of people. They mentioned, for example, Tribes; people in a neighborhood or of a particular race or nationality; low income, people of color, and pollution-burdened populations; and people injured by pesticides. Like the local officials, TOs and NGOs are each, for the most part, involved in several, diverse issues: the great majority listed at least three. A few listed one issue (e.g., drinking water, or cancer).

Twenty-one NGOs have been involved in biomonitoring, six directly and all with regard to advocacy on either policy development or to monitor a specific population. No TO had been involved in a biomonitoring effort.

Which toxic substances are of most concern?

Substances of concern[5] were similar among local officials and the TOs/NGOs. The eight most frequently listed by each group are displayed in Table 1 on the following page. The columns in the table have seven chemicals in common, with pesticides at the top of both. The other six are lead, mercury, particulate matter, environmental tobacco smoke, persistent organochlorines, and volatile organic compounds.

Concern about heavy metals as a group is noteworthy. Arsenic is on the TO/NGOs' list in Table 1, though not the local officials' list, and a few respondents checked "hexavalent chromium" and "heavy metals."

[5] *To elicit substances of concern, we provided a list of substances (as described on p. 8) and asked recipients to check each one that their organization works on. We defined "works on" as follows: "…now or within the next 12 months your organization is conducting or planning activities with regard to the substance, such as outreach, education, research, policy development, or response to public concern, or that you have had substantial staff discussion about the substance or have heard from a significant portion of your constituency that it is an important concern to them." We then asked that they select from those they checked the three that are of most concern to their organization. Later in the survey, we asked recipients to list any health risks or health effects that they did not check off previously but that are up-and-coming issues for their organization (see p. 13), to capture any substances that might have been missed in the first question. We structured similarly the question about health conditions of concern.

Respondents checked substances from a list on the survey form (and could add to the list). Because of the "pesticides" description, there is a potential underestimate in the results for pesticides because some respondents may have indicated interest in "persistent organochlorines," which were described as "e.g., DDT, PCBs, dioxins."

Table 1. Substances of Concern Most Cited by California Local Officials and Tribal and Non-Governmental Organizations *

Local Officials (N=27)	**Tribal and Non-Governmental Organizations** (N=42)
Pesticides (59%)	Pesticides (43%)**
Lead (59%)	Mercury (24%)
Environmental tobacco smoke (41%)	Persistent organochlorines (21%)
MTBE (33%)	Lead (19%)
Particulate matter (26%)	Particulate matter (19%)
Mercury (15%)	Environmental tobacco smoke (17%)
Persistent organochlorines (15%)	Arsenic (14%)
Volatile organic compounds (15%)	Volatile organic compounds (14%)***

* Total exceeds 100% because respondents listed the top three substances.
** There is a potential underestimate for pesticides, as some respondents may have checked "persistent organochlorines" when their concern is a pesticide.
*** Asbestos, drinking water disinfection by-products, and phthalates/plasticizers were also listed by 14% of the TOs/NGOs.

Which health conditions are of most concern?

The most-cited health conditions of concern were also similar for local officials and TOs/NGOs, as shown in Table 2. Considerably fewer TOs/NGOs responded to this question than to the previous question about toxic substances – 32 compared to 42. Respiratory disorders, cancer, and developmental disabilities were frequently cited by respondents. Local officials were unanimous in citing respiratory disorders.

There may have been misclassification or misinterpretation by respondents with regard to developmental disabilities, endocrine disorders, and reproductive disorders. We recommend that reproductive disorders be included in the list below for TOs/NGOs: it was the fifth highest of their concerns (22%). Local officials did not rank high either endocrine or reproductive disorders.

Table 2. Health Conditions of Concern Most Cited by California Local Officials and Tribal and Non-Governmental Organizations*

Local Officials (N=26)	**Tribal and Non-Governmental Organizations** (N=32)
Respiratory disorders (100%)	Cancer (75%)
Cancer (89%)	Respiratory disorders (47%)
Cardiovascular disease (50%)**	Developmental disabilities (34%)
Developmental disabilities (31%)	Endocrine disorders (34%)***

* Total exceeds 100% because respondents listed their top three substances.
** Cardiovascular disease was listed by 2 TOs/NGOs (6%).
*** Endocrine disorders was listed by 1 local official (4%).

Which exposure sources are of concern?

Respondents listed many exposure sources of concern in response to an open-ended question. Among the 38 NGO/TOs and 32 local officials who responded, exposure sources most frequently mentioned were:

- drinking water (several respondents specified groundwater as a drinking water source) (51%)
- air pollution, both outdoor and indoor (37%)
- agricultural sources of pesticides, including drift and runoff (24%)
- occupational exposures (usually unspecified) (23%)
- food, including subsistence fishing, commercial products, and breast milk (23%).

What subpopulations are potentially exposed more then the general population?

We asked respondents to identify specific groups that might be more exposed than the general population, to learn of populations that might be included in a biomonitoring research project. Ideas for such studies would supplement those that we learned about from our survey of researchers. (See, Section 2, Researcher Survey, page 16.)

Respondents listed some specific locations and populations with associated exposure. Most subpopulations noted, however, were less specific with regard to location, though generally considered to be potentially exposed, such as subsistence fishers in contaminated waterways, children, farm workers; cities or regions where issues of environmental exposures have been raised; and people living near sources of exposure such as transit corridors and Superfund sites. A list of potentially exposed populations appears in Appendix III, page 51.

What are the emerging environmental health issues?

In order to broaden the scope of environmental health issues for the Project, we asked respondents to list any "up and coming issues" for their organizations that they had not checked off in the questions about substances and health conditions of concern. Respondents provided a great variety of important issues, ranging among particular illnesses, conditions, populations at risk, substances and exposure sources, and policy issues. Issues listed that were not in the reports we reviewed (see Section 4, page 24) included diabetes and mold (each mentioned by several respondents); electromagnetic fields and microwaves; childhood vaccination; nose bleeds; anxiety disorders; naturally-occurring asbestos; fluoride in drinking water; styrene; meat contamination by prions, antibiotics, and steroids; genetically engineered and irradiated food; drugs and alcohol; and pollution from illegal drug labs, during production and after abandonment.

Respondents' comments regarding the Project

The survey offered the opportunity to comment on the Project, and the majority of respondents did so. We received useful cautionary advice about the planning process and about biomonitoring itself, especially with regard to participatory research, right-to-know and risk communication. These comments echo remarks made by members of the Advisory Committee at its first meeting, and at meetings of the Responsible Research Subcommittee. One respondent expressed concern that the proposed research might delay action necessary to protect the public's health.

Many respondents indicated their support for the Project, and a great majority asked to be kept informed with Project Updates.

Limitations

We received responses from local officials whose jurisdictions represent 82% of the state's population. Non-respondents were disproportionately from rural and Central Valley counties. We do not know if their concerns are the same as those of the respondents. As we are not aware of a list of all NGOs in the state with an interest in environmental health, we do not know what percent of them we reached. Our intent was to make a good-faith effort to reach as many as possible to gather their input and inform them of the Project, but we do not know that we reached all or a representative sample.

Conclusion

Based on the survey responses, pesticides are the substances of most concern for local health and environmental health officials and for non-governmental and tribal organizations. Other leading substances are heavy metals (mercury, lead and arsenic in particular), environmental tobacco smoke, persistent organochlorines, and volatile organic compounds.

Health conditions of most concern are cancer and respiratory disorders. In addition, about a third of all respondents noted developmental disorders as of concern. Half of responding local officials noted cardiovascular disease, and a third of non-governmental and tribal organizations noted endocrine disorders. With regard to exposure sources, drinking water (especially from groundwater) is of most concern, followed by air pollution (indoor and outdoor), agricultural sources of pesticides, occupational exposures, and food from all sources. These priorities will inform the Biomonitoring Planning Project selection process for biomonitoring studies to plan, outlined in Section 5.

We sought from respondents any emerging issues; no new issues were identified that are amenable to biomonitoring or within the scope of the Project. Respondents provided a lengthy list of populations at particular risk of exposure, which includes people in specified locations and occupations and those engaging in certain activities. For the most part the list is familiar to those working on environmental health issues in the State, and provides general guidance for the selection process. Some of the identified populations may be of interest in developing research projects for consideration. (See Appendix III, page 51.)

Respondents indicated ongoing interest in the Project, and gave valuable advice about both the Project planning process and subsequent implementation of the research projects that supports the project selection criteria prepared by the Responsible Research Subcommittee.

Section 2.
Researcher Survey Report

Introduction

In response to CDC's request to assess the need for biomonitoring within the State, Project staff and Working Group experts agreed that an assessment of current research activities in the state was needed to understand the research terrain for environmental and occupational health. Thus, a qualitative survey was conducted of investigators in the field, focusing primarily on their current efforts and their opinion on how biomonitoring could provide support to public health research within the State.

A qualitative survey was developed in order to assess current research efforts in environmental and occupational health. Please see Appendix IV, Survey Instrument, page 55.

The survey was intended to:

- Identify ongoing environmental health studies and/or monitoring programs with biomonitoring components or potential for biomonitoring components;
- Gather more information on laboratory methods available for biomonitoring;
- Assess laboratory gaps in supporting environmental health endeavors;
- Gather information on human specimens collected or banked for laboratory analysis;
- Gather input from investigators involved in epidemiological studies or surveillance programs as to what toxic substances, health conditions or special populations should be targeted for biomonitoring; and
- Inform researchers of this project.

The survey was given to California investigators with currently-funded studies or monitoring programs. They included:

- State and local health professionals
- Academic health researchers
- Environmental health policy experts
- Kaiser Research Division researchers

Methodology

The survey was designed to target investigators with ongoing studies in the field of environmental and/or occupational health or who are experts in the field from previous work. They were identified through key funding sources (e.g. NIEHS, NIOSH, CDC, and US EPA). In addition, researchers were asked to refer others whom they believed had relevant research. The survey instrument was mailed to identified investigators along

with an invitation letter explaining the project and asking for their participation. For most of the surveys, a follow-up call was made to ask for preference of survey administering method: interview or self-administered survey.

Results

Response rate and completeness

A total of 54 investigators was contacted. Of this number, 3 respondents replied that they currently have no relevant projects and 5 were on sabbatical or leave. From the remaining 46, a total of 22 surveys were completed and one investigator met with staff and discussed relevant projects but did not return a written survey. Thus, with 22 completed surveys of the 49 *available* respondents (subtracting the 5 investigators on sabbatical/leave), the response rate was 45% for this survey process.

Whereas the completed surveys were conducted through different methods such as face-to-face interviews, telephone interviews or self-administered questionnaires, the completeness and hence quality of these survey responses varied among the respondents. Among interviews with investigators, surveys were more likely to have greater completeness due to opportunity for probing for answers. However, most of the difference in completeness of answers applied to only a few questions regarding researchers' opinions on laboratory gaps, toxic substances which need to be monitored and additional comments for this planning project.

Questions regarding respondent's area(s) of expertise and project description made up the major component of the survey instrument. The completeness of answers to these particular questions did not vary much among the respondents, despite differences in survey administering methods. In addition, for surveys where project descriptions were vaguely answered or incomplete, a follow-up phone call was made with the respondent to increase completeness.

Current research projects

Among the investigators, some of whom were collaborators on the same project, 33 different projects were described. Please see Appendix V, Researcher Survey: Current Environmental Health Studies, page 63.

Although the toxic substances, health effects and study populations varied from study to study, certain topics were of common interest among the researchers. In the discussion below, studies that addressed more than one issue were placed in more than one e of the study focus categories .

Substances: As a proxy for substances of concern, we looked at the substances the studies addressed. Twelve studies focused on pesticides, principally organochlorines and organophosphates. Among the 6 studies addressing heavy metals exposure, lead, mercury, chromium and arsenic were mentioned as exposures of interest. Air pollutants

were the focus of 6 studies, and water contaminants were considered in 3 studies. Other toxic substances addressed included PCBs, dioxins, radiation, and PBDEs (polybrominated diphenyl ethers).

Health effects: The studies addressed a wide range of health effects believed to be impacted by environmental exposures. Ten studies focused on reproductive outcomes, including but not limited to adverse birth outcomes and birth defects. Six focused on cancer and 6 on respiratory effects, principally asthma. Four addressed neurological developmental disabilities, especially autism. Lastly, other studies addressed concerns about neurological diseases (particularly Parkinson's disease), acute illnesses resulting from pesticide poisoning, and cardiovascular diseases.

Populations: The population focus was mainly on children: 11 studies addressed health concerns among this vulnerable group. Six studies were on women of reproductive age. Seven other studies targeted populations from specific geographic regions. Three studies addressed worker's health. Finally, there were 2 studies on specific ethnic/racial groups and another on a low-income population.

Human specimen collections

Thirteen California human specimen collections were identified as a result of this survey. Please see Appendix VI, Human Specimen Collections, page 73.

Among these collection efforts are statewide programs, such as newborn bloodspots collection, and multiple specimen collection among a specific cohort by individual research studies. There are also archived samples dating back as far as the 1960's. Specimen types include blood, serum, urine, salvia, buccal cells, and hair. Though this is not a complete listing of human specimens collected within the state, it does reveal a rich resource of specimens for biomonitoring.

Interest in biomonitoring collaboration

Twenty-five studies among the respondents have human specimens collected for testing biomarkers (i.e. exposure, susceptibility, and/or effect). Among these studies, 16 are using biomonitoring to enhance exposure assessment. In response to the question about potential collaboration with the public health laboratory for biomonitoring, investigators for 20 of the studies are interested in future collaboration, of which 17 are interested in having the laboratory analyze samples, 15 in new methods development, 15 in quality assurance/ reference support; 10 in population reference range, and 1 in a laboratory referral system.

Laboratory Expansion Needs

Respondents had many ideas about how laboratory expansion could advance future research. Four respondents mentioned that labs should develop new capabilities. – methods development and/or transfer of CDC methods to state labs – to test for more

pesticides, mold, and other risks to health such as caffeine. Other researchers mentioned the need for normative data, especially among susceptible populations. Two respondents mentioned persistent organic pollutants (POPs) as an area that needs more laboratory methods development, particularly development of more inexpensive dioxin laboratory tests. One respondent indicated the need for chromium biomonitoring to assess historical exposure with a fast turn-around time for results. Four mentioned the need for standardized quality assurance or reference support for newly developed methods.

Two respondents discussed maternal serum AFP in respect to potentials for storage and suggested the laboratory should work on methods development for this type of specimen. One respondent recommended that if the laboratory is to contribute to epidemiology studies, faster sample analysis and the ability to analyze greater numbers of samples are needed in addition to quality assurance (reference support). Lastly, one respondent urged that new methods be developed which use specimens that are easier to collect (e.g., urine vs. blood) and for which less volume is required than is now the case. Use of such samples would greatly help increase participation in sample collection.

Important toxic substances to be biomonitored

Asked what toxic substances need to be biomonitored, only 10 respondents replied. Among them, two investigators stressed the importance of pesticides (including DDT) and three mentioned heavy metals, primarily arsenic and chromium. Three respondents raised PBDEs as an up-and-coming concern. Methyl mercury, benzene, phthalates, and development of measurements for air pollutants were also mentioned as important concerns, as was. iodine deficiency. A few respondents who answered this question did not list specific analytes but instead gave suggestions on how to proceed with selecting chemicals for biomonitoring (e.g. convening an expert group knowledgeable in substances of concern). One respondent commented that the driving force was really the specimen type, i.e. all chemicals are important for biomonitoring but specimen type determines which chemicals can be measured.

Limitations

There were several limitations to this survey process. The use of selected funders and other investigators as sources for identifying prospective respondents did not give Project staff a complete list of all investigators within the state. Other funding sources may reveal other projects relevant to this needs assessment, and staff is pursuing those sources. Moreover, the short timeline (April 2002-July 2002) for conducting surveys, especially during the summertime, presented certain scheduling difficulties that the project could not overcome (e.g. investigators on sabbatical or leave, vacation time during the nonacademic period). These compounded limitations resulted in a smaller number of completed surveys. Lastly, as previously mentioned, the two different methods for administering the survey (telephone interview or self-administered) may result in difference in completeness and thus, quality of the surveys. However, the difference is not significant.

Conclusion

Although the primary goal of this survey interview was to assess current research efforts and the terrain for environmental and occupational health concerns, the results can further benefit the planning process in the following ways:

1) Identify interest of investigators in collaborating with State public health labs in biomonitoring for exposure assessment;
2) Assess the perceived needs of investigators in respect to laboratory services; and
3) Identify available banked samples or currently collected samples for laboratory analysis.

Based on this assessment of current research efforts within the state, we conclude that for 20 of the studies among the 33 described, investigators were interested in collaboration with the laboratory for specific support mechanisms (e.g., to analyze samples, develop new biomonitoring methods, provide reference support for laboratory testing, or provide population reference range). The ability to analyze a greater number of samples in a given period of time (higher "throughput") emerged as a popular need for laboratory support. Lastly, we identified at least 13 programs that either are collecting or banking human specimens.

Minimally, 33 research projects are focused on environmental and/or occupational health concerns, of which 17 have a biomonitoring component. These studies differ in study population, toxic substance of concern, health effects focus, and scope, and cover a breadth of historical and current concerns surrounding environmental and occupational hazards that have public health impacts. Additionally, human specimen collection programs within the state span a wide range of specimen types and populations. Identifying interests among investigators to collaborate with the state labs provides a base for the next phase of our Project, which is to review the projects to select potential projects to include in our five-year plan.

Section 3.
Laboratory Inventory Report

Introduction

The primary purpose of the Laboratory Inventory is to assess current and past laboratory capabilities in order to plan for future laboratory capacity building. Project Staff worked with laboratory scientists to document past and current biomonitoring laboratory methods. In addition to labs within the Department of Health Services, a select group of labs from the private, governmental, and academic sectors were invited to participate. The Inventory has helped identify potential laboratory partners with cutting-edge methods and the ability to analyze many samples quickly, the first step in forming the State's laboratory network to address California's biomonitoring needs.

Methodology

An inventory survey was designed and given to laboratory scientists to complete. The questions pertain mostly to past and current biomonitoring methods. The inventory instrument was designed to gather the following information:

1. Respondent information (e.g., contact name)
2. Laboratory information (e.g., address, laboratory certification)
3. Methods description, including title, analytes, CLIA certification, instrumentation, biomatrix, current use status, proficiency testing, quality control description, interferences, and throughput
4. General laboratory expertise
5. Special instrumentation

Within the California Department of Health Services (CDHS), three laboratories directly involved with the grant were asked to describe all their past and current biomonitoring methods. These so-called "core labs" in CDHS are:

- Environmental Health Laboratory
- Sanitation and Radiation Laboratory
- Chemical Agents Biomonitoring Unit

In addition, several laboratories were identified by Project staff and Advisory Committee members as having certain strengths that would enhance laboratory capacity-building efforts. These laboratories are experienced in cutting-edge methods for testing certain analytes or have the ability to analyze large amounts of specimens in a shorter turn-around time. Project staff included them in the inventory in order to consider possibilities of future collaboration. They are:

- Pacific Toxicology

- California Department of Food and Agriculture
- CalEPA Department of Toxic Substance Control, Hazardous Materials Laboratory
- San Diego State University
- CDHS Genetic Disease Laboratory

Additional laboratories were invited but did not respond to our survey inventory within our time frame in order to be included. They included the University of California, Davis and University of California, Berkeley.

Results

Based on the different laboratories inventoried, numerous biomonitoring methods were identified to test for a wide range of chemicals and analytes. The following table shows the distribution of general chemical categories and the matrices from which the chemicals are collected.

Table 1: Inventory of Laboratory Capacity: Analytes and Sample Types for Biomonitoring

General Classification	Matrix
Alfa fetoprotein	Serum
Beta 2-microglobulin	Blood, urine
Chloride	Serum
Cotinine	Serum
Creatinine	Urine
Cresol, phenol	Blood, Urine
Cyanide	Blood
Dimethyl formamide	Urine
Dimethyl acetamide	Urine
Fipronil	Blood
Fluoride	Urine
Hippuric Acid	Blood, Urine
Mandelic Acid	Blood, Urine
Metals: Al, Sb, As, Ba, Be, Bi, Bo, Cd, Cr, Co, Cu, Fe, Pb, Mn, Hg, Mo, Ni, Se, Ag, Sr, Th, Sn, Ur, Va, Zn	Blood, Placenta, Hair, Serum, Saliva, Urine
Methyl ethyl ketone, methyl isobutyl ketone, methyl butyl ketone	Blood, Urine
Methyl hippuric acid	Blood, Urine
Methylenedianiline	Urine
Nerve agents	Urine
Polybrominated Diphenyl Ethers (PBDEs)	Adipose, Milk
Polychlorinated dibenzodioxin and dibenzofurans (PCDD/ PCDF)	Adipose, Milk
Pesticide, Organophosphate	Hand Rinses, Urine

Pesticide, Carbamates	Urine
Pesticides, Organochlorine	House Dust, Serum
Pesticides, Pentachlorophenol	Urine
Pesticides, Phenoxy Herbicides	Urine
Pesticides, triazines	Urine
Phenylglyoxylic acid	Blood, Urine
Polychlorinated biphenyls	Serum
Protoporphyrins (Pb, Zn)	Blood
Solvents/ Volatile Organic Compounds (VOC), Aromatics and Halogenates	Blood, Urine
Solvents/ VOC, Halogenated	Blood, Urine
Thiodiglycol	Urine
Unconjugated estriol	Serum

Limitations

This inventory is not a comprehensive assessment of the state laboratories' past and current capabilities in governmental, private and academic institutions. Invited respondents included those who were referred to Project staff because of unique methods or other qualities about their laboratory assets. Thus, the results refer to a select group of laboratories only and do not necessarily capture the state's full biomonitoring capabilities.

In addition, there were two refusals from the academic institutions, whose labs are well known for their methods. However, since the "core labs" were the most important to inventory as they will be directly involved in the implementation process, the other laboratories' participation was of less concern.

Conclusion

Among the labs inventoried, a significant amount and range of biomonitoring laboratory methods and compounds were identified. The commercial laboratory with the most methods shows an extensive capability for a broad range of biologic markers. However, most of its work is related to occupational or industrial hygiene and some of their methods may not be sufficiently sensitive for environmental studies (such as those conducted as part of the NHANES survey). The other laboratory with a considerable amount of methods and analytes is the Chemical Agent Biomonitoring Unit within the EHLB and SRLB laboratories, which focused primarily on pesticides.

The inventory helps us in the consideration of potential projects to plan, and is extremely useful as a baseline for the formation of a State Laboratory Network, comprised of partners from government, academia and the private sector. While this inventory informs laboratory feasibility, it should be noted that it was meant to capture current and past capabilities; future capacity is still to be determined.

Section 4.
Brief Review of Selected Environmental Health Reports Relevant to the Biomonitoring Planning Project

Introduction

Project staff reviewed a selected number of national and state reports that either addressed issues surrounding biomonitoring, addressed specific chemicals, exposures, health impacts or populations, or raised issues regarding new or emerging concerns. These reports were reviewed to provide guidance and knowledge to project staff in the development of programmatic thinking for the Biomonitoring Project; to contribute specific concerns regarding chemicals, exposures, health impacts or populations in the development of the surveys for NGO'S and local and Tribal officials; and to contribute to the development of the selection criteria that will be used to choose potential projects to include in an application for implementation funding. A list of the reports with more detailed summaries is in Appendix VII, page 76.

Results

The reports reviewed extend from discussions about the need for better interagency collaboration to strengthen environmental public health efforts to discussions of very specific concerns regarding vulnerable populations, specific chemicals and specific health outcomes. There are some common threads, important overall recommendations and insights, as well as recommendations about specific chemicals or populations to be considered.

While biomonitoring is perceived to be an important element in future identification of the connection between chemical exposure and disease, there are very few chemicals where there is adequate understanding about this relationship. CDC's recent effort at biomonitoring has produced reference ranges for a number of chemicals but there is still little known about how to interpret the meaning of these numbers when applied to research or a public health intervention.

Several of the reports discuss the monitoring of indicators as a method of tracking changes in specific environmental conditions (e.g. specific air pollutants) and/or specific disease outcomes (e.g. respiratory disease). Environmental Indicators only reflect changes in environmental conditions (e.g. number of days in exceedance of ozone levels) and are typically used to regulate environmental pollutants and to assess whether the regulatory approach is working. Environmental Health Indicators track specific diseases and their possible relationship to environmental exposures. The latter approach is most useful in an environmental public health tracking effort where the success of a public health intervention can be assessed by evaluating whether the change in an environmental condition has a potential associated change in the disease outcome. Biomonitoring can be an essential element of an environmental public health tracking program when it contributes knowledge about possible connections between exposures and health effects.

- Environmental Indicators and Environmental Health Indicators developed at the community level by and for that communities use, could be a very powerful organizing tool as well providing much needed information about potential connections between exposures and health effects.

- There is a remarkable gap between the regulatory agencies and the public health agencies on, and between, the federal and state level. Concerns identified include lack of leadership and infrastructure, lack of resources, lack of collaboration and priority setting between agencies, lack of a common vision. This lack of coordination contributes to difficulties in creating and maintaining adequate surveillance and tracking of environmental conditions and potential associated health effects, as well as creating difficulties in the development of necessary biomonitoring capacities.

- Several of the reports mentioned children as a vulnerable population that has not received adequate attention in regards to environmental research and interventions (Los Angeles/air pollution and kids; farm kids/pesticides). In particular, regulatory efforts have fallen short because risk assessment methodology still underestimates exposures to children, does not take into account multiple exposures and does not take into account children's increased vulnerabilities.

- Reproductive and developmental toxicants were mentioned in several of the reports. Endocrine disrupting chemicals were mentioned for their effect on children, the developing fetus, and in connection with breast cancer and other cancers.

- The precautionary principle – that is, the need to act to protect public health even in the absence of complete scientific proof – was cited as important to environmental policy making in the reports by advocacy and environmental organizations.

- Concerns such as air pollution and pesticides have been of concern for the last several decades (at least).

Major chemicals of concern specifically noted in the reports included:

Phthlates (especially DEP and DBP)	Solvents
Particulate matter	Organochlorines
Ozone	DDT/DDE
Environmental Tobacco Smoke	PCB's
Lead	Polyvinylchloride
Radon	Solvents
Arsenic	Nicotine
Diesel exhaust	DES
Dioxins	Bisphenol-A (BPA)
	Fluoride

VOC's	Cadmium
POP's	Manganese
Mercury	Household chemicals
Asbestos	1,3-butadiene
Pesticides (dieldrin, simazine specifically; and pesticides in general)	MTBE

Several sources of exposures were noted in the reports, including:

- Toxic air contaminants
- Drinking water contaminants
- Indoor air contaminants

Several health endpoints/diseases were noted in the reports, including:

- Respiratory (asthma/bronchitis)
- Aggravated cardiovascular disease
- Neurological toxicity
- Endocrine disruption
- Neurodevelopmental/learning disabilities/behavioral disorders
- Testicular cancer
- Breast cancer
- Mesothelioma
- Birth defects
- Reproductive disorders
- Immune disorders
- Endocrine disorders
- Cancer (in general)
- Skin Disorders
- Chronic liver disease
- Diseases of the blood (anemia)

Several major populations were noted in the reports, including:

- Children
- People with preexisting conditions
- Pregnant women
- Fetus
- Elderly
- Private well users
- Subsistence fishers
- Environmental Justice populations – this refers to poor communities and communities of color that have had disproportionate occupational and environmental exposure.

Conclusions

The reports examined for this review were not intended to represent an exhaustive literature review, but rather to highlight significant issues relevant to the Biomonitoring Project. The specific reports were known to Project staff through their own professional expertise or were recommended by knowledgeable advisors to the Project.

The reports highlighted specific chemicals, sources of exposure, possible health effects, and populations of concern. They highlighted some of the problems inherent in biomonitoring at this time including the lack of laboratory methods and reference ranges for a variety of chemicals, the lack of knowledge regarding interpretation of those values that are known and the inability, for the most part, to use biomonitoring as an effective component of environmental and occupational public health programs and interventions. They also highlighted some problem areas in State and Federal programs that contribute to the lack of knowledge regarding biomonitoring, and to the lack of coordination between and among programs necessary for developing an effective biomonitoring capacity.

Of note, several important and emerging issues were not mentioned in the reports and came to the attention of the Project Staff through a variety of other sources.This is not surprising given that such reports do not typically highlight emerging issues due to lag time in writing and publication. These issues include polybrominated diphenyl ether (PBDE), trihalomethanes (THM's) in drinking water and reproductive concerns (especially spontaneous abortions), pesticides and lymphoma, mold in indoor air and pharmaceuticals in drinking water.

Section 5.
Proposed Method for Identifying Implementation Grant Research Collaborators

Introduction

There is dramatic agreement among California's local public and environmental health officials and non-governmental and tribal organizations as to the most important toxic substances and health effects. Environmental health researchers in the focus of their current studies echo this agreement. The chemical groups of highest concern – pesticides and heavy metals – can be measured in human samples using methods, expertise and instrumentation that are present in the State laboratories. However, the testing capacity and sample throughput (the number of samples that can be analyzed in a period of time) for these chemicals is very limited.

Other environmental chemicals of concern to those surveyed are environmental tobacco smoke, persistent organochlorines, polybrominated diphenyl ethers (PBDEs) and volatile organic compounds. Laboratory capability either exists or could be developed in the state's laboratory network to measure these substances. The primary laboratory challenge is not so much in developing capability as in improving sample throughput in order to meet the needs of population-based biomonitoring.

The Needs Assessment has identified the toxic substances of concern to Californians, potential collaborators for biomonitoring projects to plan, and the existing laboratory expertise for biomonitoring within the state laboratory network.

This Section addresses the next planning phase and focuses on the process for the selection of biomonitoring projects to plan. A formal, but flexible structure is proposed that will bring to bear both scientific criteria and decision maker values, take into account the Needs Assessment results, and help us select projects that have the greatest chance of succeeding.

Under the terms of our grant from the CDC, the opportunity to expand laboratory capacity for biomonitoring activities is dependent on collaboration between the State Laboratory grantees (the Environmental Health Laboratory Branch and the Sanitation and Radiation Laboratory Branch) and non-laboratory researchers. The Laboratories' role is to analyze human samples for specific toxic chemicals as a key part of one or more research studies that include a hypothesis, identification of a study population, epidemiological analysis of the laboratory results, communication of results to the public, and other elements. Funding limitations require that collaborators must bring to the table the resources for conducting aspects of studies other than the laboratory analysis. Our survey of researchers shows considerable interest in such collaboration, and our surveys

of Tribal, local officials and non-governmental organizations show considerable support for an increased biomonitoring capacity.

This grant offers the State Laboratories the lead role in determining the nature of the research studies to be implemented and selecting collaborators. To this end, we propose the decision making structure described below. It includes selection criteria for choosing research studies, a decision flow, and a variety of participants to provide advice and make decisions. To help us create the criteria, we conducted several surveys to identify projects that are underway and include or could include biomonitoring; human samples that are banked; and chemicals, exposures, and health effects of concern to researchers, non-governmental organizations with a focus on environmental health, and local and Tribal health and environment officials. Our decision making structure is designed to maximize transparency and stakeholder concerns, optimize good science, fit into a fast-paced timeframe, and gain from the expertise of our Advisory Committee members.

In addition, we reviewed 18 environmental reports (see Appendix VII, page 76), written from both a national and state perspective, and integrated their findings into our process.

Proposed Decision-Making Structure: an Overview

Many methods and techniques are available to guide decision making. We have developed a formal decision-making structure because informal ones often result in pitting option against option, instead of evaluating each option against a defined set of criteria. Our structure focuses on the identification of explicit evaluation criteria, yet allows for flexibility in the assessment of proposed research projects. It will bring to bear both scientific criteria and decision maker values. This process requires a great deal of hard thinking about what is important in making each decision and precision about the meaning of each criterion. Our decision making structure will help us select projects that have the greatest chance of succeeding and assure that we apply the following organizing principles:

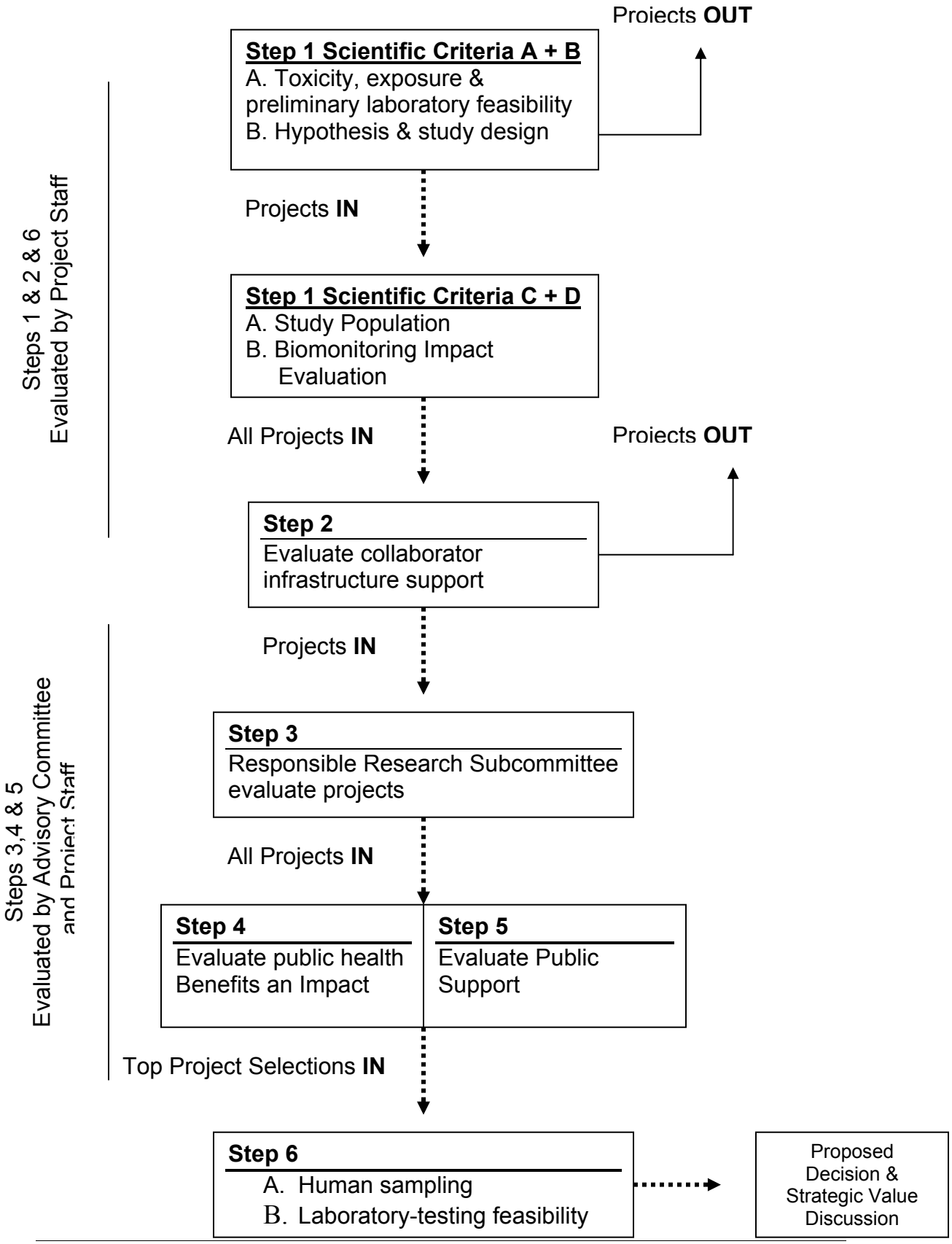
- Assure transparency by explicitly stating criteria upon which the decision was made;
- Integrate values of decision makers and stakeholders into the process;
- Allow decision makers to assert some flexibility and expertise in their choices;
- Represent all potential project alternatives in a consistent and equitable manner;
- Attempt to openly identify and communicate constraints;
- Demonstrate the concerns of multiple stakeholders;
- Safeguard that projects are not judged against each other, but rather against a list of objective selection criteria.

Additionally, we are confident that the proposed structure fits CDC criteria for funding for the biomonitoring implementation grant: the quality of the plan developed during this planning grant period; the degree to which the applicant demonstrates cooperation and integration of other public health resources (e.g. epidemiologists, schools of public health, medicine and science); and the assessment of the need for biomonitoring.

Formulating the Selection Criteria and Decision Flow

Following are the proposed selection criteria and rationale for the step-wise flow in the decision making process. In all there are 64 selection criteria (30 to be evaluated by Project Staff and 34 by the Advisory Committee) and 10-14 potential projects to be evaluated. They fall into six categories, which are ordered below. The steps will be conducted variously by the Biomonitoring Planning Staff, additional experts as needed, and the Advisory Committee. We have attempted to use Advisory Committee time judiciously by including its members' participation in key steps, while using staff for screening steps and steps requiring detailed scientific assessment (such as laboratory feasibility). Please see Diagram 1. Decision making flow on the next page.

Diagram 1. Decision making flow



Step 1. Scientific Criteria

Proposed research studies are first reviewed with regard to meeting basic requirements for exposure, toxicity, preliminary laboratory feasibility, study population, hypothesis and design. Step 1 is divided into two parts, A & B followed by C & D, because A and B are criteria that may lead to elimination from further evaluation, whereas C and D are non-exclusionary criteria. The Biomonitoring Project principal investigators, in consultation with subject matter experts when needed, will conduct this screening step.

A. Criteria to assess exposure, toxicity and cursory laboratory feasibility

All toxic substances included in projects identified through our survey efforts must meet the following three criteria:

1. Evidence for exposure in the study population;
2. Indication of toxicity in animal or human studies;
3. The chemicals to be studied pass a preliminary check for laboratory feasibility by assessing at least the following:

    - Is there a method to measure the chemical?
    - Could we do it?

Those proposals that do not meet criteria A1 or A2, but do meet A3, will be assessed for criteria 4 and 5 listed below, and if they meet at least one, will be included in further evaluation. This will ensure the inclusion of relatively new chemicals of concern where toxicity has not been completely proven and known chemicals where exposure is changing.

4. The chemical(s) is recently recognized to be of potential concern;
5. Exposure to the chemical(s) is changing or persisting.

B. Research question and study design

The following basic elements must also be present for a proposal to move forward. Before setting a proposal aside, we will contact the principal investigator of each project for clarification on any item not adequately described.

1. Study question is clearly stated.
2. Data required to evaluate the research question is clearly identified and adequate.
3. The approach and specific methods for exposure and health effect data collection are reasonable.
4. Methods for data analysis are described.

C. Identification of study population

In recognition of the disproportionate impact of toxic chemicals on racial and ethnic groups and vulnerable populations, projects will be reviewed for presence of the following criteria:

1. Exposure in vulnerable groups such as children, pregnant women, the elderly, or those with existing health conditions.
2. Exposure in racial and ethnic population groups at increased risk.

Proposed projects that include such target populations are of special interest to the CDC and will be designated as such using a checklist format.

D. Biomonitoring Impact Evaluation

Since the grant requires that we are able to evaluate the impact of biomonitoring on meeting the identified public health needs, we will note by checklist the following criteria:

1. The study provides an opportunity to evaluate one or more of the following:
    - Measures exposure levels in a population(s);
    - Measures the prevalence of elevated levels of toxic substances in a population group;
    - Measures levels of exposure in groups at increased risk or potentially more vulnerable;
    - Assesses the effectiveness of public health efforts.

Step 2: Project support provided by the proposer

Given that our project is dependent on a research collaborator, it is imperative that we are able to assess the infrastructure support provided by the proposed research. Proposed projects that cannot provide, or foresee providing, these elements will be eliminated from the pool of potential collaborators. To that end, staff will evaluate whether the study:

1. Can provide human samples;
2. Has independent funding support, or a plan to obtain it;
3. Identified staff and resources can carry out Project tasks, including data analysis and interpretation (other than human sample laboratory testing), and public health follow-up such as risk communication.

Step 3: Responsible research

The Responsible Research subcommittee of the Advisory Committee approved the following proposed criteria at a recent meeting. These criteria are based on both a literature review and discussion from the Subcommittee meetings. It should be noted that some of the criteria may not be applicable to all projects. In such cases, "N/A" will be noted for the specific criterion. Criteria marked with "N/A" will not affect the overall evaluation of the project. Additionally, Subcommittee members proposed meeting separately to review each of the projects that have advanced to this stage of evaluation. The outcome will be ranked proposals according to recommended criteria, for consideration by all Advisory Committee members as they proceed to steps 4 and 5.

A. Recruitment

1. During recruitment, the nature of the research and participation is explained to the potential study participant.
2. Appropriate educational and background materials are provided to the potential study participant at the time of recruitment.
3. Investigators explain to the potential study participant that refusal to participate in the study would not jeopardize access to health care services.

B. Use of Specimens

1. Informed consent for future use of specimen(s) for specified and/or unspecified research purposes by an approved group(s) is obtained at the time of collection.
2. There is a mechanism for the participant to ask for withdrawal of his/ her specimen(s) from the research at any time.
3. For banked specimens, if no informed consent for future use was obtained at the time of collection, investigators will request individual consent before use.

C. Results Communication

1. Disclosure of individual laboratory results, with acknowledgement of scientific validity and limitations, is offered to all participants.
2. If individual laboratory results have clinical implications, the participant will be informed and referrals will be provided.
3. When applicable, individual results will be disclosed through a face-to-face encounter that is both culturally-sensitive and allows for counseling or debriefing, if needed.
4. Results will be disclosed to participants to ensure understanding of the significance and limitations of the findings through the use of language and literacy-appropriate materials and resources.

D. Community Participation

1. Mechanisms exist for community input in the planning, implementation and results communication stages of the study.

E. Study Implications

1. Knowledge and experience gained from this study can inform policy and/ or public health actions.
2. Knowledge and experience gained from this study can inform the community to take action.

Step 4: Public health benefits and impact

Advisory Committee members will receive copies of all proposed studies organized according to the Responsible Research's ranking process and they along with the Planning Project's principal investigators will review in steps 4 and 5. Each project will also include a coversheet with previous checklist criteria indicated. We will ask that each Committee member review the project and check the criteria that apply in this step. After having reviewed all projects, each Member will select their top three projects of choice and in a summary paragraph, document their view of the principle pros and cons or limitations and strengths. This is an opportunity for Advisory Committee members to bring expertise or special considerations to the process, beyond that listed in the selection criteria. This narrative review could highlight special features such as the linkage of biomonitoring data to disease outcomes, environmental data, or measures of genetic susceptibility that add value, and other items as suggested in the list below. Proposals will be returned to project staff by November 15, 2002, and will be evaluated for more in-depth laboratory criteria in Step 6.

1. The seriousness of health effects known or suspected to result from exposure.
2. Adds to knowledge about the relationship between chemical and disease.
3. Addresses health disparities.
4. Samples a population at higher risk for exposure.
5. Could lead to the generation of normative data by providing a representative sample of Californians.
6. Offers the possibility of identifying new research initiatives.
7. Provides biomonitoring as part of an environmental health indicator and tracking process.
8. Provides the potential for increased laboratory emergency response capacity.
9. Addresses toxic substances, health effects, and exposure sources of concern as reported in the Project Needs Assessment.

Step 5: Public Support

1. The study addresses high-priority health or exposure concerns as evidenced by the Biomonitoring Planning Project's needs assessment surveys or reviewed reports .
2. Population served (sampled) is supportive of, or is likely to support, the study;

3. Community organizations and local public health partners support, or are likely to support, the study.
4. The study increases support to local public health for interpretation of biomonitoring.
5. The study increases interagency collaboration.
6. The study increases collaboration with and between community and researchers.
7. The study increases collaboration between regulatory and public health.
8. The study increases collaboration across disciplines and with health care providers.
9. The study increases support from public policy makers.

Step 6: Sampling and Laboratory-testing feasibility

As a result of the previous three review steps, proposal preferences will be tallied and ranked. High scoring proposals will be reviewed in this step by the Planning Project's principal investigators, along with subject matter experts when needed. This is the only evaluation step that will yield a quantitative value, and therefore extremely useful in thinking through the potential implementation plan.

A. Human sampling feasibility

1. Appropriate samples are obtainable.
2. Appropriate amounts of the sample can be collected or were collected and stored properly.
3. The cost to collect the required number of samples is reasonable.
4. The sample type is useful for analyzing the chemical(s) of concern.
5. Samples collected are minimally invasive. (e.g., urine vs. biopsy)
6. The potential for sample contamination by, for example, collection and storage equipment, is low.

B. Laboratory testing feasibility

1. The existence of an analytical method that can measure the chemical or its metabolite with accuracy, specificity, sensitivity and speed.
2. The method has necessary throughput.
3. The cost per sample is reasonable.
4. The time to set up and validate the method is reasonable.
5. Instrumentation is available or accessible.
6. Experienced personnel are available or can be hired
7. Contracting out some testing is an option (e.g., to speed throughput).

Developing the list of potential collaborators and projects for consideration

Criteria for potential CDC funding to implement the five-year plan that we design specifies that the funds be used principally for laboratory-related needs. Financial supprt for data analysis, infrastucture-building, and other activities will be extremely limited. For this reason, as we have spoken with potential collaborators and designed our selection criteria we have made clear that our collaboration offer is primarily for laboratory support services for biomonitoring in ongoing and future studies.

Since the laboratories will not be a source of any significant funding, in place of a request for proposals we have identified potential projects to plan through our needs assessment. From the researcher surveys, Project staff assessed current research projects for possible collaboration based on the researcher's interest and the project description, including the feasibility of human specimens collection. If researchers mentioned ideas for future studies, Project staff followed up to see whether they wanted to submit their ideas.

Similarly, if respondents to the survey of NGOs, tribal organizations, and local officials specified populations believed to be at risk for specific exposures or health effects, Project staff contacted the respondents to discuss the possibility of a study to address the concern. If there was a strong possibility that a study could be designed based and there was access to a study population for which specimens can be obtained, staff worked with individuals from relevant groups to design a study which would be submitted for consideration in this planning process. Lastly, Project staff approached the government programs (the CDHS Environmental Health Investigations Branch, Occupational Health Branch, and Childhood Lead Program, and CalEPA's Office of Environmental Health Hazards Assessment) to explain our planning process and solicit submission of their project ideas.

To ensure integrity and consistency in the consideration of all potential project options identified during the needs assessment phase, we have been working with prospective investigators on project descriptions that provide the information necessary to evaluate their projects against our selection criteria. In total we expect 10-14 potential project descriptions by October 18, 2002, to enter the project evaluation structure previously described. The project description format is below.

Format to Assess Potential Projects for inclusion in the Biomonitoring Planning Project's Implementation Plan

1. Study Question(s):
   A. Please clearly state the study question(s).
   B. What is the proposed method of testing the question(s)? (e.g., cross-sectional or case-control study design)

2. Study population:
   A. Please describe the specific study population. *(e.g. racial, ethnic, age, gender, geographic area).*
   B. What is the study sample size?
   C. How will you gain access to this study population?
   D. Who are the results from this study generalizable to?

3. Exposure(s) of interest for biomonitoring:
   A. What are the specific toxic substance(s) that will be considered?
   B. What are the source(s) of chemical exposure?
   C. Is there any evidence suggesting whether this specific population may be at greater risk for exposure?
   D. What is the existing scientific knowledge or data that support the study hypothesis?

4. Health Effect (a health effect is the result of an exposure of interest):
   A. Please describe the health effect(s), if any, related to this research project.
   B. What is the biological plausibility for the relationship between the health effect and the toxic substance(s) of interest?
   C. Is there evidence suggesting whether this specific population may be at greater risk for developing the health effect(s)?
   D. Related to the health effect(s), are there other data that you could use to support your study of this research? *(e.g. registry data, medical records.)*

5. Exposure assessment:
   A. What are the methods for data analysis for the chemical lab results?
   B. Besides biomonitoring, what, if any, additional methods will be used for assessing exposure? *(e.g. questionnaire, environmental monitoring, etc.)*
   C. What are the lab methods that you know of which can test for the specific toxic substance(s) of interest.

6. Use of Human specimen(s):
   A. What type of specimen is collected?
   B. What volume of the specimen(s) is collected?
   C. How is specimen(s) collected?
   D. How is specimen(s) stored?
   E. If applicable, how will specimen be shipped?
   F. What is the cost to collect required number of samples? (i.e. total and/or individual cost per sample)

G. What IRB approval is required for collection and/ or use of specimen?
H. How would specimen(s) be used for lab testing? (i.e. testing for biomarker of exposure, susceptibility and/or effect)

7. Recruitment

A. How will participants be informed of the nature of the research and recruited for the project?

B. If not mentioned, what types of educational and background materials are provided to the potential study participant at the time of recruitment. *(e.g., process of informed consent , whether supplemental background information for research provided)*

C. If applicable to a clinical setting, do you mention to potential study participant that refusal to participate in the study would not jeopardize access to health care services or job?

8. Use of Specimens

A. What is the process of obtaining permission for use of banked specimens? *(e.g., informed consent for future use at the time of collection, use for specified or unspecified future use, contact of participants for permission)*
B. What is the process of obtaining consent for newly collected specimens? *(e.g., informed consent for future use at the time of collection, use for specified or unspecified future use, contact of participants for permission)*
C. What mechanisms are in place for participants to ask for withdrawal of specimen(s) from the research?

9. Results Communication:

A. How will individual results be communicated to participants?
B. If results have clinical implications, how are participants informed?
C. If results have clinical implications, what mechanisms are in place for referral to services?
D. For disclosure of individual results, what types, if any, of language and literacy-appropriate materials and resources will be offered to participants?

10. Community Participation

A. How does the study incorporate community participation and input in the different stages of the study?

11. Study Implications

A. How will knowledge and experience gained from this study inform policy and/ or public health actions?

B. How will knowledge and experience gained from this study inform the community to take action? *(e.g. advocacy and/or organizing)*

12. What is the speculated time period for the following different stages of the study:

- Study design stage:
- Recruitment stage:
- Analysis stage (including data and lab):
- Results communication stage:

13. Who are the collaborators on the study?

14. What are the sources of funding for this study? Please also include in-kind funding.
    A. Current funding sources:
    B. Prospective funding sources:

15. Biomonitoring Impact
    A. How could the design of this project lead to the evaluation of the impact of biomonitoring? Here are some examples:
    - By measuring the prevalence of elevated levels in a population group;
    - By determining levels of exposure in groups at increased risk;
    - By providing levels of exposure in studies examining health effects;
    - By determining whether levels are higher in potentially more vulnerable populations;
    - By assessing the effectiveness of public health efforts.

    B. What are the resources necessary to provide this type of evaluation?

Making the final decision – The December 2002 Advisory Committee meeting

Finally, with all previous information at hand, we have identified the projects that are most likely to succeed as part of our implementation plan. Project Staff will come to a conclusion as to which projects will be pursued based on the guidance of the Advisory Committee and laboratory evaluation criteria in step 6. This information will be presented at an Advisory Committee meeting proposed for December 12, 2002.

At this meeting, we will ask Advisors to consider the potential implementation project or projects from the perspective of strategic value. Strategic value refers to California's particular assets from the perspective of the CDC, and how they are taken advantage of by the proposed study. Given the competitive nature of the implementation grants, this discussion is to consider projects with respect to how they may stand out on a national level. The following are some examples of characteristics of projects with strategic value:

- Exposure is linked to (indoor or outdoor) air quality
- Exposure is linked to pesticides
- Study population represents California's diversity
- Study includes Kaiser Permanente
- Study involves the California Cancer Registry
- Study involves the California Birth Defects Monitoring Program.

Discussions and negotiations with collaborators

By mid-December 2002 we will have confirmed our directions for the California Biomonitoring Implementation Plan and will have six months in which to work out the

details of a high-quality Plan with collaboration partners. The plan will encompass strategic, operational, organizational, and resources planning with collaborators, and embody elements of strategic planning for the laboratories.

Appendix I

Non Governmental Organizations, Tribal Groups, and Local Health and Environmental Officials* Survey Instrument

* The following survey instrument was sent to non-governmental and tribal organizations as described in Section 2. It was sent to local Health Officers and Directors of Environmental Health with the following changes:

- Question 3 was eliminated (since local officials are responsible for all populations)
- In Question 4 and throughout the phrase, "health risks" was changed to "toxic substances"
- In Question 6, the phrase "health effects" was changed to "health conditions."

State of California – Health and Human Services Agency
Department of Health Services

California Biomonitoring Project - Needs Assessment Survey

Your name:	
Title:	
Your organization's name:	
Address:	
City, State, and Zip:	
Phone:	
Fax:	
E-mail:	

My organization is primarily (mark only one):

☐ national

☐ statewide

☐ regional within California (e.g. covers the San Francisco Bay Area, or the Los Angeles Basin)

☐ local (neighborhood, city or county, or similar geographic area)

I am responding for (check one):

☐ a local branch of a larger organization

☐ the entire organization.

Please send me quarterly updates on the project. ☐ Yes ☐ No

1. Has your organization been involved in biomonitoring? ☐ Yes ☐ No

If yes, please describe that involvement:

2. What are the primary environmental health issues for your organization?

3. Does your organization try to represent the concerns of any particular group(s) of people (e.g., racial, ethnic, age, gender, geographic area)? ☐ Yes ☐ No

If yes, which one(s)?

4. Following is a list of potential health risks. Please mark with an "x" each one that your organization works on. Use the "Other" spaces at the bottom to add any risks you work on that are not listed.

By "work on," we mean that now or within the next 12 months, your organization is conducting or planning activities with regard to the risk, such as outreach, education, research, organizing, advocacy, or lobbying; or, that you have had substantial staff discussion about the risk or have heard from a significant portion of your constituency that it is an important concern to them.

	Risk to Health	**My organization is working on this [mark all that apply]**
a.	Arsenic	
b.	Asbestos	
c.	Carbon monoxide	
d.	Drinking water disinfection by-products	
e.	Environmental tobacco smoke	
f.	Flame retardants/brominated compounds (e.g., PBDEs)	
g.	Formaldehyde	
h.	Lead	
i.	Mercury	
j.	MTBE (gasoline additive)	
k.	Ozone	
l.	Particulate matter [especially fine particulates]	
m.	Persistent organochlorines (e.g., DDT, PCBs, dioxins)	
n.	Pesticides (both agricultural and non-agricultural)	
o.	Phthalates/plasticizers	
p.	Polycyclic aromated hydrocarbons (PAHs) (e.g.benzo(a)pyrene)	
q.	Radionuclides from natural sources (e.g., radon, uranium)	
r.	Volatile organic compounds (e.g. benzene)	
s.	Other… [please write its name]	
t.	Other…[please write its name]	

5. Of the health risks checked above, which three are of most concern to your organization? Please type or write the corresponding letters in the box below (e.g., for lead, ozone, and pesticides, you would write “h”, “k”, “n”):

Comments:

6. Following is a list of health effects. Please mark with an "x" each one that your organization works on. Use the "Other" spaces at the bottom to add any risks you work on that are not listed.

	Health Effect	**My organization is working on this [mark all that apply]**
a.	Birth defects (e.g., neural tube defects, heart defects)	
b.	Cancer (e.g., leukemia, breast cancer, non-Hodgkin’s lymphoma)	
c.	Cardiovascular disease (e.g., high blood pressure, heart disease)	
d.	Chronic liver disease and cirrhosis	
e.	Developmental disabilities (e.g., learning and behavioral disorders, autism, cerebral palsy, mental retardation)	
f.	Diseases of the blood (e.g., sickle cell anemia, aplastic anemia, methemoglobinemia)	
g.	Endocrine disorders (e.g., infertility, endometriosis)	
h.	Immune disorders (e.g., Lupus, chronic fatique syndrome)	
i.	Neurological problems (e.g., Parkinson’s, multiple sclerosis, Alzheimer’s)	
j.	Reproductive disorders (e.g., spontaneous abortions)	
k.	Respiratory disease (e.g., asthma, chronic bronchitis, emphysema)	
l.	Skin disorders (e.g., rashes, eczema)	
m.	Other… [please write its name]	
n.	Other… [please write its name]	

7. Of the health effects checked above, which three are of most concern to your organization? Please type or write the corresponding letters in the box below (e.g., for cancer, endocrine disorders, and developmental disabilities, you would write “b”, “e”, “g “):

Comments:

8. Are there any health risks or health effects that you have not checked above, but that your organization thinks are "up-and-coming" issues? Please list them here:

9. Please list particular sources of chemical exposures that your group is concerned about (e.g., drinking water, an occupational exposure, outdoor or indoor air pollution).

10. Among your constituents, are there any specific groups of people that you have reason to believe are exposed or have been exposed to potentially toxic substances more than the general population? (For example, people in a particular neighborhood or area where there is or used to be contamination; people who catch and eat fish from a specific polluted stream or lake; people who are exposed in the course of their work; or a group of people who have a health problem that may be linked to potentially toxic substances.)

If so, please describe the specific group(s):

11. If you have any other comments about the California Biomonitoring Planning Project or biomonitoring in general, please add them here.

Thank you! We will send the results of this survey to those who have completed and returned it to us. Please return this form to **Lori Copan** at **lcopan@dhs.ca.gov**.
You may also copy and fax it to attn: **Lori Copan, 510/540-3022**, or mail it to
Lori Copan
Environmental Health Laboratory Branch
2151 Berkeley Way, Rm. 334
Berkeley, CA 94704

Thank you for your time and consideration. If you have any questions, please call Ms. Copan at 510/849-5044.

Appendix II

Lists of Survey Respondents

Non-Governmental Organizations and Tribal Organizations
Local Health Officers and Directors of Environmental Health

Non-Governmental Organizations and Tribal Organizations

Alliance for Lung Cancer Advocacy, Support & Education (ALCASE)
Bear River Band of Rohnerville Rancheria
Breast Cancer Action
Breast Cancer Fund
California Communities Against Toxics
California League of Conservation Voters
California League of Conservation Voters Education Fund
California Rural Legal Assistance Foundation
California Valley Miwok Tribe
Californians for Alternatives to Toxics
CALPIRG
Center for Environmental Health
Clean Water Action
Commonweal
Communities for a Better Environment
Community & Children's Advocates Against Pesticide Poisoning
Community Clean Water Institute
Community First Coalition
Del Amo Action Committee
Elk Valley Rancheria
Environmental Center of San Luis Obispo
Environmental Health Association
Environmental Health Coalition
Environmental Justice Coalition on Water, and Merritt College Environmental Technology
Environmental Working Group
Hunter's Point Shipyard Restoration Advisory Board
Inter-Tribal Council of California, Inc.
Latino Issues Forum
Literacy for Environmental Justice
Manchester/Point Arena Band of Pomo Indian
Marin Breast Cancer Watch
Morongo Band of Mission Indians
National Environmental Trust
Natural Resources Defense Council
Pesticide Action Network
Pesticide Education Group
Physicians for Social Responsibility, Los Angeles
Physicians for Social Responsibility, San Francisco Bay Area
Santa Clara Center for Occupational Safety and Health
Scotts Valley Band of Pomo Indians
Sherwood Valley Rancheria
Sierra Club Arguello Group
Silicon Valley Toxics Coalition

Trinidad Rancheria
Urban Habitat
West County Toxics Coalition
Women's Cancer Resource Center
Yurok Tribe

Local Health Officers and Directors of Environmental Health

Department or Agency	Responded for Both Environmental and Public Health
Alameda County Environmental Health Department	yes
Berkeley City Health Department	yes
City of Vernon Health & Environmental Control	yes
Colusa County Health & Human Services	no
Contra Costa Health Services	yes
County of Riverside Community Health Agency	yes
Glenn County Health Services	no
Humboldt County Department of Health and Human Services	yes
Imperial County Department of Public Health Services, Environmental Health Division	no
Kings County Department of Public Health	yes
Lake County Health Services Department, Environmental Division	yes
Los Angeles County Department of Health Services	no
Monterey County Health Department	yes
Napa County Health & Human Services Agency	no
Orange County Environmental Health	no
Orange County Health Care Agency, Public Health Services	no
Sacramento County Departmen of Health and Human Services	no
San Benito County Health & Human Services Agency	yes
San Bernardino Department of Public Health	no
San Diego County Department of Environmental Health	no
San Diego County Health and Human Services Agency, Community Epidemiology Division	no
San Francisco Department of Public Health	yes
San Joaquin County Environmental Health Department	no
San Luis Obispo County Public Health Department	yes
San Mateo County Health Services Agency	no
Santa Barbara County Environmental Health Services	no
Shasta County Public Health	no
Sonoma County Department of Health Services, Environmental Health Division	yes
Sutter County Health Department	no
Tulare County Health and Human Services Agency	yes
Ventura County Department of Public Health	no
Yolo County Health Department	yes

Appendix III

Populations Listed by Local Health and Environmental Health Officials, Non-Governmental Organizations, and Tribal Organizations As Potentially Exposed to Toxic Substances in the Environment

Survey respondents provided narrative answers to the question, "Among your constituents, are there any specific groups of people that you have reason to believe are exposed or have been exposed to potentially toxic substances more than the general population?" Some responders indicated that they were listing a concern they had heard about and passing that concern on via the survey.

The responses are sorted below based on whether they are related primarily to an activity, geographic location, proximity to a source, occupation, or "other." Many cross over more than one category, but all are listed below only once. The list below does not reflect the frequency that an item was listed. For items listed multiple times with a different descriptor, the descriptor is under the main item (for example, see Subsistence fishing).

Activities

Recreational swimming in polluted waterways
- San Diego Bay

Subsistence fishing and
- African-Americans
- Asian-Americans
- New Mormon Slough (San Joaquin County)
- Old Mormon Slough (San Joaquin County)
- San Diego Bay
- San Francisco Bay
- Stockton Channel (San Joaquin County)

Geographic Location

Alpaugh
Bay View Hunters Point (San Francisco)
Big Valley Rancheria (mercury)
Carson
City of Commerce
Daly City/Midway Village
Del Amo
East Palo Alto
El Em Rancheria (mercury)
Huntington Park
Los Angeles Basin
Marin County and
- Mill Valley (asthma)
- San Anselmo (cancer)
- San Geronimo (cancer)

Mexico/California border
North Richmond

Parchester Village (Richmond)
Richmond
Robinson Rancheria (mercury)
Rodeo
Santa Barbara County, oil processing facility
Santa Fe Springs
South Gate
Southeast Los Angeles
Southeast San Francisco
West Berkeley (transit corridors, industry)
West Oakland
Wilmington

Proximity to a Source – Residents Near the Following Locations

Agricultural areas where pesticides are applied and
    strawberry fields
    vineyards
BKK Superfund site (West Covina)
Dry cleaners
Fort Ord clean-up areas
Green waste and composting generators
Hamilton Field (Marin County)
Hazardous waste truck washing facilities
ICTF (Los Angeles)
IES Medical Waste Incinerator (Oakland)
Lead smelters
Los Angeles International Airport
Manufacturing plants
Marley Cooling Tower (San Joaquin County)
McCormick and Baxter Creosote Company (San Joaquin County)
Natural background levels of arsenic, radionucleides
People served by water systems that exceed federal standard for arsenic
Petrochemical refineries
Port of Long Beach
Port of Los Angeles
Port of Oakland
Power plants (older plants)
Railroad right-of-way (arsenic in ties, pesticide application)
Red Star/LaSaffre Yeast (Oakland)
REMCO facility (Sherwood Valley Rancheria)
Residents of older housing (lead, asbestos) and
    Tribal members in Oakland
Schools near sources of toxic substances (e.g., near agricultural fields)
Source of groundwater contamination south of Sebastopol
Stryrofoam cup factory (Larkspur)

Sulphur Bank Mercury Mine (Lake County, El Em Band of Pomo Indians)
Transit corridors
Tritium Labeling Facility (Berkeley)
Vermiculite processing plant (now closed) (Oakland)
Vinyl chloride cleanup site (West Oakland)
Water treatment sludge used for compost

Occupation

Casino workers (Tribal casinos)
Dentists and dental workers (mercury)
Farm workers and family farmers, and their families (Latinos, South East Asians)
People exposed to second-hand smoke in the workplace
Produce packing and distribution workers
Semiconductor and allied electronics industry operations
Welders and platers

Other

Children
Children exposed in schools
Fetuses
Low-income communities
Low-income immigrant workers
    Day laborers
People of color
    African Americans
    Latinos
    Native Americans
People with asthma
People with compromised immune systems
Pregnant women
Women of childbearing age

Appendix IV

Researcher Survey Instrument

ENVIRONMENTAL AND OCCUPATIONAL HEALTH RESEARCHER SURVEY

Section 1. Professional Background, Occupation and Focus

Today's Date: _____

Name:	**Title:**
Employer:	**Degree(s):**

1) Which of these best describes your professional expertise? *(please check all that apply)*

___Epidemiology
___Toxicology
___Chemistry
___Industrial Hygiene
___Health Policy
___Biology
___Public Health Research
___Other (please specify: _____)
___Clinical practice (please specify specialty: _____)

2) Which of these area(s) best describes the focus of your work (i.e. what is your area of focus)? *(please check all that apply in each of the section)*

Health Hazards (Exposures)	**Health Effects (Disease and Conditions)**	**Special Populations**
__Persistent organic pollutants (e.g. PCBs and dioxins) __Heavy Metals (e.g. mercury and lead) __Pesticides (e.g. organophosphates and carbamates) __Air contaminants (e.g. toluene and fine particles) __Drinking water contaminants, including pathogens __Endocrine Disrupters (e.g. phthalates) __Other (please specify: _____)	__Birth Defects and Reproductive Outcome __Developmental disabilities (e.g. cerebral palsy, autism, and mental retardation) __Asthma and respiratory diseases __Cancer, including childhood cancer __Neurological Diseases, including Parkinson's, Multiple Sclerosis and Alzheimer's __Other (please specify:_____)	__Children's Health __Women's Health __Elderly Health __Worker Health __Ethnic/National Population (please specify group: _____) __Other (please specify:_____)

Section 2. Current Research Work

3) Are you currently involved in any funded environmental health, occupational health study(ies) or disease monitoring programs based within California? __**YES** __ **NO** *(If* **NO***, skip to 13)*

3A) If **YES**, please describe each of your study(ies) or program(s) by answering the questions below:

Study 1 ***Please describe one of your funded studies/ programs in the following questions***

Note: For the next set of questions, please choose one of your studies to answer the following questions.
*** If you have more than one study or program, please refer to Section IV to continue to describe each of the additional studies.*

4) What is the title of this study or program?

5) What is the time period of funding for this study or program?

6) What other collaborators, if any, are on the study or program?

7) What health issue(s) or health relationship(s) between exposure and disease are being considered in this study or program?

8) What is the study population (i.e. who are they and where are they from)?

9) Does this study collect human samples for laboratory analysis? __**YES** __ **NO** *(If* **NO***, skip to 9B)*

9A) If **YES**, please fill out the table below:

Type of Human Sample(s)	**Type of Biomarker:** *(please check all that applies and specify what is measured/ identified in sample)*	**Where are your samples analyzed?** *(please check all that apply and indicate name of laboratory)*	**What lab methods are used for this specimen analysis?** *(If unknown, please provide lab contact person for project)*	**Problems encountered with biomonitoring**
1.	___Biomarker of Exposure: *specify:* ___Biomarker of Susceptibility: *specify:* ___Biomarker of Effect: *specify:*	___State Lab *(name:_____)* ___Federal lab *(name:_____)* ___Private Lab *(name:_____)* ___Academic lab *(name:_____)* ___Other *(name:_____)*		
2.	___Biomarker of Exposure: *specify:* ___Biomarker of Susceptibility: *specify:* ___Biomarker of Effect: *specify:*	___State Lab *(name:_____)* ___Federal lab *(name:_____)* ___Private Lab *(name:_____)* ___Academic lab *(name:_____)* ___Other *(name:_____)*		

9B) If **NO**, could you think of some type of human biomonitoring that would improve the quality of your study or program?
Please describe briefly:

11) Are there any environmental monitoring components in this study or program? __**YES** __ **NO** *(If* **NO***, skip to 12)*
* If **YES**, please fill out the table below:

What substance(s) is monitored?	What kinds of environmental sample(s) is being collected?	Please briefly describe any problems encountered from environmental monitoring.
1.		
2.		
3.		

12) Would you be interested in future potential collaboration with the State Public Health Laboratory in human biomonitoring for this study or any future studies in this area? __**YES** __ **NO** *(If* **NO***, skip to 13)*

12A) If **YES**, please indicate how the State labs could best support your research study in human biomonitoring? *(please check all that apply):*

___Analyze samples.
___Develop new human biomonitoring methods.
___Provide quality assurance or reference support for lab testing.
___Provide population reference range.
___Other, *please specify:* _____

Section 3. Suggestions for Biomonitoring Project

13) Are there any gaps or areas for further development at the laboratory science level that would enhance your future research?

14) In your opinion, what toxic substance(s) do you think we should biomonitor (i.e. as an assessment of exposure) in order to address public health needs within the State? *(If possible, please suggest specific populations whom we should biomonitor these toxic substance(s))*

15) Please suggest any other investigators with ongoing or planned studies which have current or potentials for biomonitoring whom we should interview for this planning project:

Name of Principal Investigator/ New Programs	**Organization**	**Contact Info** *(if known)*	**Health Issue**
1.			
2.			
3.			

16) Do you have any additional suggestions or comments?

***Section 4*:** Additional studies

If you are involved in additional studies, please continue to fill out the following pages about your other studies.

Study 2 ***Please describe a 2nd funded study/ program that you are involved with in the following questions***

17) What is the title of this study or program?

18) What is the time period of funding for this study or program?

19) What other collaborators, if any, are on the study or program?

20) What health issue(s) or health relationship(s) between exposure and disease are being considered in this study or program?

21) What is the study population (i.e. who are they and where are they from)?

22) Does this study collect human samples for laboratory analysis? __**YES** __ **NO** *(If* **NO**, *skip to 22B)*

22A) If **YES**, please fill out the table below:

Type of Human Sample(s)	**Type of Biomarker:** *(please check all that applies and specify what is measured/ identified in sample)*	**Where are your samples analyzed?** *(please check all that apply and indicate name of laboratory)*	**What lab methods are used for this specimen analysis?** *(If unknown, please provide lab contact person for project)*	**Problems encountered with biomonitoring**
1.	___Biomarker of Exposure: *specify:* ___Biomarker of Susceptibility: *specify:* ___Biomarker of Effect: *specify:*	___State Lab *(name:_____)* ___Federal lab *(name:_____)* ___Private Lab *(name:_____)* ___Academic lab *(name:_____)* ___Other *(name:_____)*		
2.	___Biomarker of Exposure: *specify:* ___Biomarker of Susceptibility: *specify:* ___Biomarker of Effect: *specify:*	___State Lab *(name:_____)* ___Federal lab *(name:_____)* ___Private Lab *(name:_____)* ___Academic lab *(name:_____)* ___Other		

		(name:_____)		

22B) If **NO**, could you think of some type of human biomonitoring that would improve the quality of your study or program?
Please describe briefly:

23) Are there any environmental monitoring components in this study or program? __**YES** __ **NO** *(If* **NO***, skip to 24)*
* If **YES**, please fill out the table below:

What substance(s) is monitored?	**What kinds of environmental sample(s) is being collected?**	**Please briefly describe any problems encountered from environmental monitoring.**
1.		
2.		
3.		

24) Would you be interested in future potential collaboration with the State Public Health Laboratory in human biomonitoring for this study or any future studies in this area? __**YES** __ **NO**

24A) If **YES**, please indicate how the State labs could best support your research study in human biomonitoring? *(please check all that apply):*

___Analyze samples.
___Develop new human biomonitoring methods.
___Provide quality assurance or reference support for lab testing.
___Provide population reference range.
___Other, *please specify:* _____

Appendix V

Researcher Survey: Current Environmental Health Studies

Researcher Survey: Current Environmental Health Studies

Investigator & Organization	Study Title & Type	Funding Period	Health Issue	Study Population	Samples Collected & Biomonitoring	Environmental Monitoring	Laboratory & Methods	Interest in Biomonitoring Collaboration?
Baker, Dean UC Irvine	"Childhood Lead Assessment in Tijuana, MX"	1996-2001	exposure assessment of lead	children ages 2-6 in Tijuana	biomarker of exposure: blood-lead	soil, ceramic, pottery, dust paint	Baja-California state labs	yes: 1)provide quality assurance and 2)provide population reference range
Bhatia, Rajiv SF DPH	"Organochlorine Pesticides and Male Genital Anomalies"	8/98-8/03	Do Organochlorine pesticides act as exogenous endocrine disrupters?	Bay area mothers/ children from late 60's and 70's	Biomarker of exposure: OC pesticides; serum	none	HML: GC with EC and MS	no
Bhatia, Rajiv SF DPH	"San Francisco Healthy Homes for Healthy Airways"	11/00-10/02	Indoor air triggers for asthma	clients from SF DPH clinics	none	none	none	no
Bradman, Asa UC Berkeley	"Center for the Health Assessment of Mothers & Children of Salinas (CHAMACOS)"	1998-2003	pesticide/ OP/ endocrine disrupter/ allergen, endotoxin exposures to neurodevelopment, growth and respiratory disease	low-income Hispanic population from Salinas Valley	biomarker of exp & susceptibility: urine, blood, breast milk	pesticides in house dust; allergens & endotoxin in dust	CDC, State, Academic (UCB, U of Wash), Private (Batelle Labs): LC/MS/MS, GAAS, Flow cytometry, GCMS	yes: 1)analyze samples, 2) dev. new methods, 3) provide quality assurance or ref support 4) provide population reference range
Bradman, Asa UC Berkeley	"Pesticide in Amniotic Fluid"	2002	exposure study of pesticides	pregnant women referred for amniocentesis	biomarker of exposure: amniotic fluid	none	CDC	yes:1) analyze samples, 2) provide quality assurance 3) provide ref ranges

Chang, Daniel UC Davis	"Improving Welding Toxic Metal Emission Estimates in CA"	7/01-12/02	examining the emission factor for welding operations involving high chromium content alloys	N/A	none			Yes: 1) provide quality assurance/ ref support for lab testing
Cohn, Barbara Public Health Institute			prenatal organochlorines on breast cancer and reproductive outcomes	Child Health and Development Studies-pregnancy cohort from 1959-67	biomarker of exposure:serum archive with new samples in now adult children-organochlorines	none	Mt Sinai School of Medicine; USC	yes: 1)analyze samples, 2) dev. new methods, 3) provide quality assurance or ref support 4) provide population reference range; overall open to new ideas & future collaboration
Croen, Lisa Kaiser Research Department	"Center for Children's Environmental Health-Environmental Epidemiology of Autism-Childhood Autism Risk from Genetics & the Environment"	July 2001-June 2006	Exposures to PCBs, pesticides, metals (particularly mercury) in relation to autism and developmental delay/ MR risk. Genetic and environmental interactions; lipid metabolism, cytokine expression, mRNA profiles, DNAP polymorphism	Children born in CA (selected counties), between ages 24-60 months who are: 1)autism cases; 2)mental retardation/dev delay controls; and 3) typically developing controls	biomarker of exposure: blood-mercury, PCBs, and pesticides; urine-several xenobiotics; biomarker of susceptibility: blood-lipid metabolism, cytokine profiles, mRNA profiles, genetic polymorphisms, peptide profiles; buccal cells-genetics	none	UC Davis lab	yes: 1)analyze samples, 2) dev. new methods, 3) provide quality assurance or ref support 4) provide population reference range
Das, Rupali CDHS Occup Health Branch	"Laboratory Reporting for Pesticide Illness Reporting" - monitoring program	1999-2002	(cholinesterase-inhibiting) pesticide exposures and primarily acute health endpoints (pesticide-related illnesses)	workers in CA	Biomarker of exposure: blood--cholinesterase	none	3 private volunteer labs: Ellman method--Boehringer manheimkit	Yes: 1)analyze samples, 2)develop new b/m methods, 3) provide quality assurance or ref support for lab testing

Das, Rupali CDHS Occup Health Branch	"Sentinel Event Notification System for Occupational Risk (SENSOR)--Pesticides, CA" --surveillance program	1997-2002	Surveillance for exposure to pesticides and any health endpoint (primarily acute)	workers in CA	none	none	none	Yes: 1)analyze samples, 2)develop new b/m methods, 3) provide quality assurance or ref support for lab testing
English, Paul CDHS EHIB		to 12/02	exposures to pesticides and water contaminants to risk of testicular cancer	all CA males	none	none	none	no
English, Paul CDHS EHIB	SB 702	to 6/03	Health Tracking initiative a pilot project on asthma/ reproductive outcomes and traffic exhaust exposure	Alameda residence, particularly in Kaiser or on Medi-Cal	none	none	none	yes
Fenster, Laura (collaborator on CHAMACOS) CDHS EHIB	"Center for the Health Assessment of Mothers & Children of Salinas (CHAMACOS)"	1998-2003	pesticide/ OP/ endocrine disrupter/ allergen, endotoxin exposures to neurodevelopment, growth and respiratory disease	low-income Hispanic population from Salinas Valley	biomarker of exp & susceptibility: urine, blood, breast milk	pesticides in house dust; allergens & endotoxin in dust	CDC, State, Academic (UCB, U of Wash), Private (Batelle Labs): LC/MS/MS, GAAS, Flow cytometry, GCMS	yes: 1)analyze samples, 2) dev. new methods, 3) provide quality assurance or ref support 4) provide population reference range
Grether, Judy CDHS EHIB	"CA Center for Autism and Developmental Disabilities Rearch and Epidemiology (CADDRE)"- surveillance program	2001-2006	Protein markers in newborn bloodspots and some gentic susceptibility to autism; environmental exposures will be considered later in course of study	children in 6 bay area birth counties	biomarker of susceptibility: newborn bloodspots	none	NIH: immunoassay techniques	yes: 1) analyze samples

Grether, Judy CDHS EHIB	"Autism Twin Study"	proposal submitted for additional 5 years	Looking at concordance for autism in zygosity; this would be larger twin study than previous ones	statewide; twins or multiple births from 1987-present	biomarker of susceptibility: newborn bloodspots	none	NIH and GDB	yes: 1) analyze samples
Harnly, Martha (collaborator of CHAMACOS) CDHS EHIB	"Center for Health Assessment of the Mothers & Children of Salinas (CHAMACOS)"	1998-	pesticide exposures and neurodevelopmental/ behavioral problems, delayed growth, and respiratory symptoms/ diseases; also exposure to env. allergens/ respiratory irrants to respiratory symptoms/ diseases	children in Salinas County	Biomarker of exposure: organophosphate pesticide metabolites; urine	house dust to detect pesticide exposure in child's immediate environment	CDC lab	
Harnly, Martha CDHS EHIB	"Pesticide Exposure in Women of Reproductive Age: a US-Mexico Border Study"	after 2003	exposures to non-persistent pesticides in women of reproductive age who currently are not pregnant	women age 18-45 (not pregnant but can) in Imperial County, CA	Biomarker of exposure: orghanophosphate metabolites	none	CDC lab	

Pessah, Isaac UC Davis	"Center for Children's Env & Disease Prevention"	9/01-8/06	trying to understand environmental factors which influence genetic susceptibility on autistic symptoms; considering such things as Hg on immune system and blood composition for biomarkers of exposure	children in CA aged 3-5 with autism	biomarkers of exposure: 1) blood: testing for organic halogens and pesticides, 2) urine: testing for PCBs, insecticides, organic halogens & Hg, 3) hair: Hg & heavy metals biomarkers of Effect: blood: test for complete lipid analyisis (biochemistry effect in fatty acids) Biomarker of Susceptibility: buccal Cells: DNA markers	none	UC Davis lab	yes: 1)analyze samples, 2) dev. new methods, 3) provide quality assurance or ref support 4) provide population reference range
Peters, John USC	"Genetics, Air Pollution and Respiratory Disease in Children and Young Adults"	4/2002-3/2007	Indoor and outcoor air and non-malignant respiratory disease and asthma	children and young adults in Southern California (n=12,000)	biomarker of susceptibility: DNA-genetic polymorphism--buccal cells Biomarker of Exposure: cotinine from salivary samples with dip sticks	air monitors in 12 communities of criteria air pollutants	USC lab: Taqman method for multiple polymorphism	yes: develop new human biomonitoring methods
Reynolds, Peggy CDHS EHIB	"Regional variations in breast cancer in California"	through 6/2003	various environmental factors and breast cancer	teachers from different regions in CA	biomarkers of exposure: urine-1OHP and HAs			
Reynolds, Peggy CDHS EHIB	"Childhood Leukemia and Environmental Exposures"		genetic & environmental factors causing childhood leukemia	400 children in Bay Area and Central Valley	biomarker of susceptibility: maternal and child's blood	dust swipes and meters to measure EMF		

Ritz, Beate UCLA	"Parkinson's Environment and Gene"	2000-2005	historical pesticide exposure and Parkinson's Disease	all incidence cases in Central Valley from 1998-2003; control and sibling control-matched	biomarker of susceptibility: DNA and lymphocytes; biomarker of exposure: blood serum--organochlorines & storage	none	UCLA; UCSD	Yes: 1)analyze samples, 2)develop new b/m methods, 3) provide quality assurance or ref support for lab testing
Ritz, Beate UCLA	"Traffic-related Air Pollution and Adverse Birth Outcomes in Los Angeles"	2001-2004	criteria air pollution and effects on adverse birth outcomes such as low birth weight, preterm delivery and birth defects	all women in LA who gave birth in 1994-2000 and also a nested case control of those women who had lbw and preterm delivery in specific zip codes for 2001-2003	none	yes; air criteria pollutants from air monitors through Air Board	none	Yes: 1)analyze samples, 2)develop new b/m methods, 3) provide quality assurance or ref support for lab testing
Ritz, Beate UCLA	"Cancer Incidence in Nuclear Workers" --expanded follow-up	2000-2003	radiation and chemcial exposure on cancer incidence	workers in Rocketdyne Nuclear Facility	none	none	none	none
Shaw, Gary CA Birth Defects Monitoring Program		10/01 to 2006	biotransformation genes intereact with environmental exposures (e.g. smoking, medications, occupational and some chemicals) to cause birth defects	children with birth defects in 1987-2003 in CA and some Maryland	bomarker of susceptibility: 40 genes, DNA	none	Texas A&M; CHORI; PCR-base amplication; high resolution throughput multiplexing for more than 1 gne run simultaneously	yes: 1) analyze samples

Shaw, Gary CA Birth Defects Monitoring Program	"Oral Clefts and folate pathway genes"	9/01 to 9/04	3 genes that may be associated with oral clefts	children with oral clefts and those w/out any structural malformations in CA	biomarker of susceptibility: newborn bloodspots-- DNA	none	Texas A&M; PCR-based test	no
Shaw, Gary CA Birth Defects Monitoring Program	"Homocysteine Regulation and Congenital Heart Defects"	10/01 to 10/06	genes and exposures that may alter homocysteine metabolism	children with heart defects and those w/out any structural malformations	biomarker of susceptibility:buccal cells & newborn bloodspots-- DNA	none	Texas A&M: PCR	no
Shaw, Gary CA Birth Defects Monitoring Program	"Cener for Excellence"-- CDC funding for state-based monitoring program	10/02-10/07	risk factors for whole variety of birth defects, genetic etiology in DNA sampling	infants with and w/out structural malformations in CA	biomarker of susceptibility: buccal cells-- DNA for infant and parents	none	Texas A&M and CHORI: PCR amplification	yes: 1) analyze samples 2)develop new human biomonitoring methods
Simmons, Bart CalEPA HML (w/ Myrto Petreas)	"Adipose and Breast Cancer"	2002 (already in analysis phase)	contaminants accumulated in adipose (e.g. PCBs, dioxin and PBDEs) and breast cancer	breast cancer patients and Stanford clinic	biomarker of exposure: adipose--PCBs, dioxins and PBDEs	none	Hazardous Materials Lab: high resolution GC-MS	no b/c already in end stages
Steinhaus, Craig UCSF	"Arsenic Lung Accumulation Study"	end 7/02	arsenic accumulation in lung	King County, CA and Churchill County, NV (population-based)	biomarker of exposure: lung, bladder, skin, kindney, liver cadaver specimens	drinking water arsenic levels	U of Washington	Yes
Steinhaus, Craig UCSF	CA Arsenic Methylation Study"	end 7/02	variation in humans in arsenic methylation	King County, CA and Churchill County, NV (population-based)	biomarker of exposure: urine for arsenic levels	drinking water arsenic levels	U of Washington	Yes

Underwood, Marilyn CDHS	"Program to conduct site-specific health activities"	10/2002-9/2006	asthma/ chromium sensitivity and chromium exposure	anyone anywhere in CA	biomarker of exposure: arsenic--hair, urine, feces; uranium in urine; DDT in blood; chromium from radioimmunoassay ?	*possible if needed and approved:* dioxins, PCBs, and Hg in fish; Pb and other metals in dust, DDT in radishes	CDC-EHL (federal); Washington State University lab(academic); Mayo Clinic (academic); National Medical Services in PA (private)	Yes: 1)analyze samples, 2)develop new b/m methods, 3) provide quality assurance or ref support for lab testing, 4) referal to other labs
Windham, Gayle CDHS EHIB	"Organochlorine Levels and Menstrual Cycle Function in Laotian Immigrants"	1995-2002	organochlorines and reproductive health (menstrual cycle function)	Laotian women in Oakland and Richmond	biomarker of exposure: organochlorines; biomarker of effect: menstrual cycle function	none	HML	Yes: 1) analyze samples; 2)develop new human biomonitoring methods; 3)provide quality assurance 4) reference range 5) referral systems to other labs
Windham, Gayle CDHS EHIB	"Chlorination By-products in Drinking Water and Reproductive Health"	end 2002	Drinking water chlorinated by-products and reproductive health (as measured by semen quality, pregnancy outcome, menstrual function)	CA; specifically Santa Clara Kaiser members	biomarker of effect: urine--menstrual cycle effect; semen quality	water samples testing from water companies (chlorinated by-products)	UC Davis lab	Yes: 1) analyze samples; 2)develop new human biomonitoring methods; 3)provide quality assurance 4) reference range

Van Den Eeden, Stephen Kaiser Research Department	"Genetics and Environmental Risks for Parkinson's Disease"	1994-2005	risk of PD associated w/ a variety of environmental expsoures (e.g. home gardening, occupational exposures, diet, smoking) and also susceptibility genes; some gene-environment interactions	newly diagnosed Parkinson's Disease patients who are members of Kaiser Permanente 1004-95 and 2000-2004 (CA-based)	biomarker of susceptibility: blood-genes	none	Stanford and Parkinson's Institute lab--PCR	not sure at this point
Van Den Eeden, Stephen Kaiser Research Department	various studies of ambient air pollution	1992-2004	ambient air pollution (e.g. PM, ozone, CO, NO2, etc) and health effects such as cardiovascular, chronic respiratory disease (ER and hospitalizations)	Kaiser Permanente patients	none	none		not sure at this point

Appendix VI

Researcher Survey: Human Specimen Collections

Human Specimens Banks and Collection Programs

Contact Person	Organization	Description	Type of Specimens	Comments
Cohn, Barbara	Public Health Institute	Child Health and Development Study--longitudinal study of pregnant Kaiser members (1959-1967)	Banked maternal serum; possibly semen in future	Cohort study from the 1960's w/ possible follow-up of 2nd & 3rd generation
Cunningham, George & Marty Kharrazi	Genetics Disease Branch (GDB)	Newborn Bloodspot Screening; all newborns in CA; collection since 1982; Bloodspots through needle prick of newborn's heel	Newborn bloodspots (three hole punches on filter paper)	Difficult for biomonitoring due to minute amounts; mostly for biomarkers of susceptibility
Cunningham, George & Marty Kharrazi	Genetics Disease Branch (GDB)	Maternal Serum-Alpha Fetal Protein (MS-AFP); Pregnant women who came in for MS-AFP test; 65-70% of pregnant women get this screening minus Kaiser specimens; Year 2000-Year 2002 collected	Maternal serum	currently banking AFP tests from Orange County, San Diego and Imperial County (further banking possible in other counties at relatively small cost); unable to test for certain heavy metals b/c possibility of contamination from needles used to draw blood;
Cunningham, George & Marty Kharrazi	Genetics Disease Branch (GDB)	N=25,000 Women coming in for pregnancy tests (different purposes; reasons can be for birth control or to get pregnant); not all women are pregnant and some women may have multiple samples of urine; San Diego County	Urine	Possibilities of testing exposure from time to pregnancy since there are multiple samples of urine (women get pregnancy test before starting birth controls or trying to get pregnant); good representation of women from lower SES
Cunningham, George & Marty Kharrazi	Genetics Disease Branch (GDB)	At time of birth, umbilical cord attached to placenta is clamped on both sides and cut. Blood within is banked (no metal contamination from clamps). Blood remains in hospital for 7 days and then is released to GDB who only collects the serum	Fetal Cord Blood	Certain San Diego areas
Das, Rupali	DHS Occupational Health Branch	Laboratory Reporting for Pesticide Illness; statewide workers in California	Blood	Done on as needed basis (from pesticide illness)

Contact Person	Organization	Description	Type of Specimens	Comments
Eskenazi, Brenda	UC Berkeley	CHAMACOS	maternal urine & blood (prenatal); cord blood; breast milk; infant blood & urine (up to 24 months)	601 pregnant women in Medi-Cal in Salinas Valley being served by two community clinics
Pessah, Isaac (PI of Center) & Hertz-Piciotto (PI of Epi Study)	UC Davis	Center for Children's Environmental & Disease Prevention; children 2-5 with autism and controls (including those with mental retardation and those considered “normal”)	Blood, urine, hair and buccal cells	Just started collection in Summer of 2002
Peters, John	USC	Children's Health Study; N=1,200 children and young adults in S. CA	Buccal cells, saliva	Testing of cotinine in saliva
Reynolds, Peggy	CA-DHS, EHIB	CA Teacher Study; N=3000 female teachers; 3 sets of 10 mL aliquots and 1 set of 40 mL aliquots remaining	24 hour urine samples	
Ritz, Beate	UCLA	Parkinson's Environment and Gene (PEG)--registry of Parkinson's Disease incident cases in Central Valley (1998-2003)	Blood, serum, lymphocytes	Population include those exposed occupationally (acute & high-dose) and those exposed by residential proximity (chronic low-dose)
Shaw, Gary	CA Birth Defects Monitoring Program	CDC funded Center for birth defects research among various states	Buccal cells	Children in 11 birth counties in CA w/ birth defects
Underwood, Marilyn	ATSDR	Program to conduct site-specific health activities	Blood, hair, urine	All of CA
Windham, Gayle (et al.)		Women’s Repro Health Study: 404 women, 18-39, collected urine daily for 3-6 menstrual cycles.	Urine—now consolidating to 1 cycle/woman. Saliva—saved??	Kaiser, Santa Clara Co., early 1990’s. Urine analyzed for hormones and cotinine. Saliva for cotinine. Questionnaire, geocoding of residence (TTHM levels).
Windham, Gayle	CDHS, EHIB	Laotian Women’s Health Study: 50 women, 18-40, collected daily urine during 3 menstrual cycles.	Daily urine: <1-2 mls./day left. Blood—minimal remaining.	Immigrants in SF Bay area, questionnaire incl. detailed fish consumption. Urine analyzed for hormones; blood for mercury, PCBs, PBDEs, OCC pesticides.

Appendix VII

Summary of Major Environmental Health Reports

1. Toxic Chemicals: Long Term Coordinated Strategy Needed To Measure Exposures in Humans
2. America's Environmental Health Gap: Why the Country Needs A Nationwide Health Tracking Network
3. DC and ATSDR'S Proposed Plan for an Environmental Health Tracking Network
4. National Report on Human Exposure to Environmental Chemicals
5. California Comparative Risk Project Summary Report
6. Title: Environmental Protection Indicators for California (The EPIC Report)
7. California Environmental Health Indicators
8. Neighborhood Knowledge For A Change: The West Oakland Environmental Indicators Report
9. Indicators For Occupational Health Surveillance (Draft)
10. Toxic Beginnings: A Lifetime of Chemical Risk in the First Year
11. In Harm's Way: Toxic Threats to Child Development
12. Generations At Risk: How Environmental Toxicants May Affect Reproductive Health In California (Executive Summary)
13. State of the Evidence: What is the Connection Between Chemicals and Breast Cancer?
14. Hooked on Poison: Pesticide Use in California 1991-1998
15. Poisoning The Air: Airborne Pesticides in California
16. Trouble on the Farm: Growing Up With Pesticides in Agricultural Communities
17. Forging New Alliances: Building a Common Vision for California's Environment
18. PPIC Statewide Survey: Special Survey on Californians and the Environment

1. Toxic Chemicals: Long Term Coordinated Strategy Needed To Measure Exposures in Humans
Authors: United States General Accounting Office
Date: May, 2000

Summary: GAO conducted a review of state and federal efforts to collect and use human exposure data and an evaluation of the barriers hindering further progress in this area. Of the 1,456 toxic chemicals reviewed, only 6% (81 chemicals), are or have been measured in the general population (through NHANES or NHEXAS). The portion measured ranged from 2% of chemicals prioritized for safety testing to about 23% of those chemicals most often found at Superfund sites and considered to pose a significant threat to human health. Even for those that are measured, information is often insufficient to identify smaller population groups at risk. Three main barriers limit federal and state's ability to make more progress. First, federal and state laboratories lack the capacity to conduct measurements needed to collect human exposure data. For most of the reviewed chemicals, no lab method exists for measuring the chemical in human tissue. The second barrier relates to the lack of information to put any results in context. More information is needed on general exposure levels as well as the relationship of exposures to potential health effects. The third barrier relates to the need for a commitment to long term coordinated strategies, particularly at the federal level between EPA and HHS, to work together on collection issues, agency goals, identifying at risk populations and working with the states. The report reviews the variety of efforts at collecting human specimens and identifies the following gaps in human exposure data:

1. number of chemicals measured remains limited;
2. sampling is not sufficient to identify highly exposed groups;
3. human exposure data is limited despite federal efforts to identify communities of concern;
4. information and infrastructure gaps point to the need for strategic planning and coordination;
5. laboratory capacity needs development, particularly at the state level and methods for measurement of chemicals need development;
6. information is needed to interpret human exposure measurements; and
7. stronger interagency efforts are needed for planning and coordination. The report pointed out that individual agency priorities contribute to difficulties in coordinating efforts (such as the differences between the priorities of public health agencies and the priorities of regulatory agencies).

Relevance: This report provides support for increasing the laboratory capacity for measuring toxic chemicals in human tissue while outlining the potential benefits of biomonitoring and the inherent difficulties in developing methods and interpreting the results. There is strong support for coordination and planning between federal agencies, and state and federal agencies, in order to meet the challenges of developing a coordinated strategy for measuring exposures to toxic chemicals in humans. Report outlines examples of how state officials use human exposure data, including

epidemiological investigations, surveillance, investigation of citizen concerns, investigation of accidental releases and investigation of disease clusters.

Support for existing criteria: Development of baseline exposure levels; development of exposure levels in at risk populations; increasing laboratory capacity and methods development; using biomonitoring as inherent part of exposure assessment and epidemiological studies.

2. America's Environmental Health Gap: Why the Country Needs A Nationwide Health Tracking Network
Authors: The Environmental Health Tracking Project Team of The Pew Environmental Health Commission at the Johns Hopkins School of Hygiene and Public Health.
Date: September, 2000

Summary: The Commission proposes a Nationwide Health Tracking Network to address the 'basic environmental health gap', that is, the lack of critical knowledge that could document possible links between environmental hazards and chronic disease which would then allow for the development of prevention strategies. The report proposes that we are limited in knowing if there is a link between pollution and the increase in chronic disease because we don't have any tracking of environmental health factors. This is an ideal time to propose this tracking because of the increase in understanding of the genome which increases our ability to understand the genetic/exposure/disease link. Biomonitoring is an important part of the tracking of environmental health factors.

The **goals** of the proposed tracking network include the following:

1. identify populations at risk;
2. establish the relationship between environmental hazards and disease;
3. guide intervention and prevention strategies;
4. identify, reduce and prevent harmful environmental exposures;
5. improve the public health basis for policymaking;
6. enable the public's right to know about the environment; and,
7. track progress towards achieving a healthier nation and environment.

The Network would be comprised of five key components including:

1. a national baseline tracking network for diseases and exposures;
2. a nationwide early warning system for critical environmental health threats;
3. state pilot tracking programs to test diseases, exposures and approaches for national tracking;
4. federal investigative response capability; and,
5. tracking links to communities and research.

The Commission identifies a number of priority chemicals, exposures, diseases and conditions, as well as state-specific concerns for environmental health tracking. State and federal officials were interviewed to determine concerns and priorities. Concerns

included a lack of collaboration, lack of leadership and infrastructure, lack of data necessary for tracking, lack of availability of public information and networks for dissemination of information, a lack of collaboration and priority setting between public health and regulatory agencies and a lack of connection to efforts at creating environmental health indicators. The health outcomes designated as priorities for tracking include asthma and respiratory diseases, neuro-degenerative diseases, developmental disabilities, reproductive disorders, endocrine and metabolic disorders, cancer and birth defects. The priority chemicals include persistent organic pollutants such as PCB's and dioxin, heavy metals (lead and mercury), pesticides, air contaminants such as toluene and particulates, and drinking water contaminants.

Relevance: The report supports the need for an Environmental Health Tracking Network as an essential part of effective public health practice. Biomonitoring can be an important part of tracking as a means of monitoring the exposures in populations over time as well as in acute emergencies or in specific exposed populations. Addresses need to develop leadership, strengthen science and improve reporting capacity. Some danger here in assuming that tracking disease and exposures will lead to a cause/effect relationship.

Support for existing criteria: Consistent with CDC's proposed uses for biomonitoring in studies. Use of TRI data as potential indicator of exposure for biomonitoring. Tracking in specific at risk populations.

3. CDC and ATSDR'S Proposed Plan for an Environmental Health Tracking Network
Authors: CDC and ATSDR
Date: August, 2001

Summary: This report is CDC's and ATSDR's response to the PEW Environmental Health Commission report calling for the development of a Nationwide Environmental Health Tracking Network. This report by CDC and **ATSDR proposes a ten year plan to**

1. address the concerns of; tracking hazards, exposures and health outcomes;
2. integration and use of data for tracking and linking hazards,
3. exposures and outcomes;
4. infrastructure development at state and federal level for environmental public health capacities;
5. collaboration between federal agencies (especially CDC and ATSDR) and between state and federal agencies;
6. coordination of all activities.
7.

Support of community interests and scientific research would be facilitated through the funding of five Centers of Excellence for training and research and partnering with communities. Grants for technical assistance and infrastructure development would be provided to 15-25 states to pursue pilot tracking projects.

Relevance: Relevance to the Biomonitoring Project exists to the extent that biomonitoring is considered an essential element of the development of environmental health tracking. Partnering with and between community and researchers.

Support for existing criteria: Same as for previous report.

4. National Report on Human Exposure to Environmental Chemicals
Author: CDC
Date: March, 2001

Summary: This Report is a new publication that will provide an ongoing assessment of the exposure of the U.S. population to environmental chemicals using biomonitoring. The report provides exposure information about people participating in CDC's ongoing national survey of the general U.S. population—the National Health and Nutrition Examination Survey (NHANES). The first release of the Report is restricted to general U.S. population data for the year 1999. The Report surveyed 5,325 individuals and biomonitored 3,812. The first Report contains information about levels of 27 chemicals in the U.S. population. The substances include metals (e.g., lead, mercury and uranium), organophosphate pesticide metabolites, phthalate metabolites, and cotinine. Because the sample is relatively small, more data will be needed to confirm these findings. Nonetheless, this first Report provides an indication of reference values for specific chemicals as biomonitored in the U.S. population.

The major findings of the Report are;

1. first time information about exposure levels for the U.S. population;
2. reference range values for physicians and health researchers;
3. a decline in blood lead levels among children since 1991-1994, highlighting the success of public health efforts to reduce lead exposure to children;
4. reduced exposure of the U.S. population to environmental tobacco smoke as evidenced by a decrease in cotinine levels, again highlighting some public health success in reducing tobacco smoking;
5. a better assessment of children's and women's exposure to mercury which will allow better estimates of potential health risks; and
6. data to assist with setting priorities for research on phthalates, particularly on DEP and DBP which are produced in lower quantities but have higher metabolite levels in the general population.

Relevance: This is the first ever study to produce reference ranges of chemicals in the general population. More research needs to be done on reference ranges for other chemicals, exposures in different populations determined by race, gender age, urban/rural residence, education level, income and special exposure populations. Additional research is also needed to determine the meaning of the levels of chemicals in human specimens including the relationship to exposure and disease and whether public health interventions are working in various situations.

Support for existing criteria: Consistent with CDC's outlined uses. Development of baseline exposures: increased lab capacity; recommends looking at special populations.

5. California Comparative Risk Project Summary Report
Author: Office of Environmental Health hazard Assessment, California Environmental Protection Agency
Date: 1994

Summary: The California Comparative Risk Project was the initial attempt to prioritize environmental problems in California and to address the process of environmental decision making. The impacts on human health, ecosystem health and social welfare were categorized and ranked into high, medium and low impact based on the severity of the impact and the number of people affected. The issues of education (including public participation in decision making), environmental justice and economics were also considered in entire project. The highest human health impacts included particulate matter, ozone, environmental tobacco smoke, lead, pollutants of natural origin (radon, natural radiation, and arsenic), diesel exhaust, dioxins, volatile organic chemicals, pesticides, and persistent organochlorines. The major health effects were respiratory disease (asthma and bronchitis), aggravated cardiovascular disease, developmental or neurological toxicity, and premature mortality. Those at most risk were children, people of color, people with preexisting medical conditions, at risk populations (pregnant women, developing fetus, elderly, private well users, subsistence fishers) and individuals living in "hot spots" (African- American and Hispanics living in areas with high air pollution, regions with geologic radon, regions with contaminated biota affecting water quality and fish, regions with water high in arsenic).

Relevance: Many of the issues identified at that time are still issues. This was an early attempt to link environmental indicators with health indicators.

Support for existing criteria: All concerns identified at that time that are still a concern are included in our process.

6. Environmental Protection Indicators for California (The EPIC Report)
Author: California Environmental Protection Agency
Date: October, 2001

Summary: This document proposes to examine the progress that California has made in protecting the environment through examining several scientifically objective indicators that reveal trends in the environment, and which in turn may impact human health. Given the rapid economic and population growth in California, there are dramatic environmental changes. Data regarding seven principle environmental indicators are presented, which are divided into air quality, water (quality, supply and use), waste management, pesticides, transboundary issues, human health and ecosystem health. The report lists known contaminants that are monitored for each source (water, air, etc.) and categorizes each environmental indicator by the availability of data- type I, II, or III, with type I indicators having adequate data to present a status or trend. The environmental

topics frequently extend beyond specific toxicants that directly impact human health. The directive for the report is to help Cal-EPA create measurable goals and standards by which progress in environmental, regulatory protection can be ascertained. The report only includes six indicators in the chapter on environmental exposure impacts on human health although it is acknowledged that many of the indicators in other sections reflect trends that could have an impact on human health. The indicators that are included are ones that "mainly focus on specific adverse health effects that have strong associations with environmental exposure to pollutants. These are: surveillance of persistent organic pollutants in body tissues and fluids; lead; mercury; mesothelioma associated with non-occupational exposure; exposure to environmental tobacco smoke; and, asthma emergency room visits related to ozone and particulate matter. Of these, four have the potential for biomonitoring.

Relevance: The focus of this process is to create a results-based management system for environmental protection by a primarily regulatory agency. Because of this focus, many indicators that may be important for human health, but may not be easily measured in a cause-effect manner, are not included in the human health arena. In addition, while it is important to do biomonitoring for those human health indicators where appropriate, one would not want to rely on this process alone to develop preventive, public health policy and strategies. This report represents the difference of thinking between a regulatory approach and a public health approach.

Support for existing criteria: All of the exposures and outcomes reflected in the indicators have been considered in our process.

7. California Environmental Health Indicators
Author: Environmental Health Investigations Branch, California Department of Health Services
Date: July, 2002

Summary: This report identifies 18 indicators for environmental health chosen on the following basis: indicators of environmental health should include (1) states of human health that are caused by, or are associated with environmental exposures; (2) measures of environmental quality that have the potential to affect human health; and (3) sociodemographic measures that place pressure on the environment, or increase the possibility of exposure in vulnerable populations. It is very difficult to identify direct links between environmental exposures and health outcomes. Indicators used in this report do not represent a direct relationship between exposure and disease, but rather illustrate a trend in health, environmental quality or sociodemographics, which is considered important for monitoring the overall health of the population.

Relevance: This is a first step in California to link environmental indicators with health outcome indicators. Relevant to the Biomonitoring Project to the extent that biomonitoring could be included as part of the indicators and tracking process.

Support for existing criteria: Consistent with the 'benefits public health' criteria

8. Neighborhood Knowledge For A Change: The West Oakland Environmental Indicators Report
Author: Pacific Institute for Studies in Development, Environment and Security
Date: January, 2002

Summary: This report describes the identification of 17 environmental indicators created by a community process for a local neighborhood in West Oakland. The indicators were chosen partially so the knowledge acquired by identifying the problems could result in community action to improve or eliminate the problem. The report describes each indicator and addresses why the indicator is important, who it affects and what can be done about it. **Four of the indicators related most directly to health were;**

1. there are 5X more toxics per person generated by facilities as reported to the Toxics Release Inventory than other Oakland residents;
2. the West Oakland zip code registered the highest in toxic air releases in all of Oakland in 1998;
3. West Oakland residents had the second highest health risk from air pollution in 1997; and,
4. children are 7X more likely to be hospitalized for asthma than the rest of California children.

This juxtaposition of environmental data and health data for a local area shows one of the ways such a project is enlightening for a community.

Relevance: The relevance to the Biomonitoring Project is in highlighting a specific community that has a disproportionate share of exposures and health problems. Supports usefulness of looking at indicators at the local level.

Support for existing criteria: Special populations; assistance to local communities

9. Indicators For Occupational Health Surveillance (Draft)
Author: Council of State and Territorial Epidemiologists and National Institute of Occupational Health
Date:

Summary: This draft report outlines 13 indicators that could be used for occupational health surveillance. They all address situations where a public health intervention can be taken to address the problem. Only one of them has any biomonitoring capability, that of lead poisoning surveillance.

Relevance: Creating indicators where a public health intervention can address the problem is in line with the CDC and PEW reports. The relevance to the Biomonitoring Project extends only if there is biomonitoring as part of the surveillance.

Support for existing criteria: none

10. Toxic Beginnings: A Lifetime of Chemical Risk in the First Year
Author: National Environmental Trust
Date: 2001

Summary: This report focuses on the special risk to Los Angeles children from cancer-causing toxic air contaminants. In 1999, representative Waxman's office analyzed the levels of 10 toxic air pollutants monitored in the Los Angeles region and found that combined they posed a lifetime cancer risk of over 400 times greater than considered acceptable by the US EPA. The National Environmental Trust took these same data and analyzed further and found that the lifetime cancer risk accumulated by a child in his or her first year of life in Los Angeles when the chemicals are combined and the special vulnerabilities of children are taken into account, is at least twice the average lifetime risk accumulated by an adult over a one-year period. This means that in only two months, a child born and living in Los Angeles accumulates a lifetime's acceptable risk of cancer. An adult accumulates a lifetime risk in only four months. Most of the cancer risk is from 1,3 butadiene, formaldehyde and benzene. These are mostly from mobile sources. The report states that even if the carcinogens in Los Angeles air were cleaned up, a child would still exceed the lifetime risk by age four. This is because EPA's cancer risk goal does not take into account the special vulnerabilities of children and the cumulative effects of being exposed to several carcinogens at one time. California law SB 25 looks specifically at children's vulnerabilities to air pollution and these three chemicals meet the guidelines for revision under this law.

Relevance: The relevance to the Biomonitoring Project is to highlight a special population- children, in a particular geographic area- Los Angeles, that has a particular exposure-air pollution.

Support for existing criteria: special populations (children) linked with particular exposure; consistent with CDC guidelines.

11. In Harm's Way: Toxic Threats to Child Development
Author: Greater Boston Physicians for Social Responsibility
Date: 2000

Summary: This report examines the contribution of toxic chemicals to neurodevelopmental, learning, and behavioral disabilities in children. The report outlines nine reasons for scrutinizing toxic exposures related to these disabilities.

1. An epidemic of developmental, learning, and behavioral disabilities has become evident among children.
2. Animal and human studies demonstrate that a variety of chemicals commonly found in industry and home can contribute to behavioral and learning disabilities.
3. A deluge of highly technical information has created communication gaps within the field of child development. (4) Although genetic factors are important, they should not be viewed in isolation.

4. Neurotoxins are not just a threat to children. In some instances, adverse impacts are seen at current exposure levels.
5. Vast quantities of neurotoxic chemicals are released into the environment each year.
6. Environmental releases often lead to human exposures with potential for harm.
7. The historical record clearly reveals that our scientific understanding of the effects of toxic exposure is not sufficiently developed to accurately predict the impact of toxicants, and our regulatory regime has failed to protect children.
8. Protecting our children from preventable and potentially harmful exposures requires a precautionary principle that can occur only with basic changes in our regulatory process. The specific chemicals of concern that are outlined in the report include lead, mercury, manganese, nicotine, dioxins/PCB's, pesticides, solvents, cadmium, and fluoride. These interfere with normal brain development and have long tern consequences; they can also bioaccumulate in body tissue and be passed along via breast milk or to developing fetus.

Relevance: Special population-children; and special endpoint- neurodevelopmental disabilities (e.g.; autism). Some of the chemicals mentioned have biomonitoring potential.
This is a compelling problem because so little is known about the neurotox or endocrine disrupting potential of most chemicals so this could add to the field of knowledge.

Support for existing criteria: Same as above in relevance.

12. Generations At Risk: How Environmental Toxicants May Affect Reproductive Health In California (Executive Summary)
Author: Physicians For Social Responsibility and The California Public Interest Research Group Charitable Trust
Date: 1995

Summary: This report brings together information about reproductive health effects of selected chemical exposures with California chemical use and emissions data. It quantifies the use and release of 78 "listed chemicals" (in the TRI or PUR) which have been identified as reproductive and developmental toxicants by government agencies or by weight of the evidence as published in the scientific literature, as evaluated by the authors. In addition to this list, the report identifies and discusses the reproductive and developmental effects of additional chemicals for which release data was not available or for which the weight of evidence was not deemed sufficient for listing but which are suspected of having reproductive or developmental effects. Some of the chemicals of concern include lead, mercury, solvents (glycol ethers, toluene, zylene, styrene, perchlorethylene), pesticides, manganese, and dioxin. Endocrine disruption is a frequently occurring mechanism of toxicity in chemicals causing reproductive and developmental toxicity. The report found that one-half of all releases listed as reproductive and developmental toxicants was in Los Angeles and Orange counties. It also cites a report on pesticide use by CALPIRG showing that one-half of 46 school

districts and thereby, one-quarter of all children in California, are exposed to pesticides on school grounds. It also cites high pesticide releases in the Central Valley. Policy recommendations include minimization of chemical use and exposure, adoption of the precautionary principle for policy making, and public and worker right to know, right to education, and right to training.

Relevance: Focus on endocrine disruption**.** This report utilizes potential exposure data with specific endpoints and mentions some possibly exposed populations. Some of the chemicals are ones for which biomonitoring is an option.

Support for existing criteria: Linking with emissions/exposure data; specific endpoints/ specific population; chemicals are some of the ones that we have considered.

13. State of the Evidence: What is the Connection Between Chemicals and Breast Cancer?
Author: The Breast Cancer Fund and Breast Cancer Action
Date: 2002

Summary: Breast cancer rates have continued to climb in the United States and other industrialized countries since the 1940's but at this point, still over 50% of breast cancer cases remain unexplained by the characteristics and risk factors associated with the disease. This report examines the evidence for an environmental link to breast cancer. Ionizing radiation is the only known environmental cause of breast cancer. The report outlines three levels of strengths of evidence for environmental association. The strongest evidence linking chemicals to breast cancer concerns natural and synthetic estrogens. Included in this are drugs such as DES as well as xenoestrogens which are synthetic, hormone disrupting chemicals. These include bisphenol-A (BPA), polyvinylchloride (PVC), pesticides (dieldrin and simazine in particular), household cleaning agents (methylene chloride, lindane), solvents, and 1,3,butadiene (an air pollutant created by manufacturing processes). The next level of evidence is one which designates a probable link between chemicals and breast cancer. Included in this are certain chlorinated chemicals which are also endocrine disrupters. These are DDT/DDE and PCB's. While both these chemicals have been banned since the 1970's, both can still be found in the body fat of humans and animals and in breast milk. Other chemicals in this probable category include polycyclic hydrocarbons (PAH'S) and dioxin. Dioxin may be the most prevalent of all toxic chemicals in body tissue. Chemicals in the third level of evidence- a possible link between chemicals and breast cancer, include heptachlor and phthalates The report offers a specific research agenda for attacking the problem. (1) Phase out toxic chemicals. (2) Enact "sunshine" laws and enforce environmental protection laws. (3) Practice healthy purchasing. (4) Offer corporate incentives. (5) Monitor breast milk. A basis for all this is the precautionary principle.

Relevance: This report summarizes the evidence for endocrine disrupting chemicals influence on breast cancer and calls specifically for biomonitoring of breast milk.

Support for existing criteria: Specific endpoint/specific chemicals/specific population (women). Consistent with CDC outlined uses; consistent with 'public health benefits'

14. Hooked on Poison: Pesticide Use in California 1991-1998
Author: Pesticide Action Network. This report is one in a series of reports by Californians for Pesticide Reform
Date: 1999

Summary: Analysis of state pesticide use data shows that between 1991 and 1998 more than 1.5 billion pounds of pesticides were applied in California. During this eight-year period, Californians significantly increased their reliance on pesticides, with reported use up 40%, an average increase of 7.2 million pounds per year. The report states that at the time of the report, approximately one-third of the total pounds of pesticides used in any given year were known to be particularly toxic to humans, as acute poisons, or as known or probable carcinogens, reproductive or developmental toxicants, or neurotoxins. These are labeled the California 'Bad Actors'. Overall 'Bad Actors' use decreased some in this time period (primarily due to a reduction in the use of methyl bromide and metam sodium) but the use of carcinogenic pesticides increased 127% during this same time period. This is particularly disturbing given what was the concurrent increase in age-adjusted incidence of cancers that have been associated with pesticide use- childhood leukemia, brain tumors, non-Hodgkin's lymphoma, testicular cancer and some forms of breast cancer. In addition, the use of reproductive and developmental toxicants rose 43% in the first 4 years of the time period and then dropped 16%. The use of endocrine disrupting pesticides increased by 14%. Policy recommendations include the use of prevention and the precautionary principle as the basis for policy making; mandating the reduction of pesticide use, especially the most toxic pesticides; increase support for alternatives; and, develop and implement consumer education strategies.

Relevance: This report focuses on pesticide use, especially the most toxic pesticides. Some of the pesticides mentioned are candidates for biomonitoring.

Support for existing criteria: Evidence for exposure and indication of toxicity; has biomonitoring capability.

15. Poisoning The Air: Airborne Pesticides in California
Author: California Public Interest Research Group Charitable Trust. A report in a series by Californians for Pesticide Reform.
Date: 1997

Summary: This report utilizes data from 1995 on use of pesticides categorized as Hazardous Air Pollutants (HAPs) and Toxic Air Contaminants (TACs) in California. Although only limited research was (and is) available on pesticides in air, studies have consistently found pesticides in air, rain and fog. In addition, many communities complain of health effects that they believe are related to pesticides in the air. Air monitoring for pesticides has shown that of the 26 pesticides monitored under the state TAC program in 1995, 19 were detected at schools or other public buildings near the

application sites. Drift is an established fact for some pesticides on the TAC list. Over 46 million pounds of pesticides were sprayed from aircraft in 1995, accounting for 20% of the total California use. Millions of Californians live close to areas where highly mobile air borne pesticides are used. The report also discusses the use of structural fumigants as a contribution to indoor air pollution.

Relevance: This report is not current but the trends related to increasing air pollution and concern over pesticides is consistent.

Support for existing criteria: Specific focus on air borne pesticide pollution.

16. Trouble on the Farm: Growing Up With Pesticides in Agricultural Communities
Author: Natural Resources Defense Council
Date: October, 1998

Summary: Children who live on or near agricultural land, or whose families work in the fields, are likely to be the most pesticide exposed subgroup in the United States. They come in contact with pesticides through residue on their parents clothing, dust tracked in the house, contaminated soil in outdoor play areas, food brought directly from the fields, and contaminated well water. They may also accompany their parents to work in the field, raising their exposures even higher. Many of the children at most risk are form migrant families who are typically poor and may have limited health care access. In addition, these children may experience drift in fields close to their homes. NRDC has previously shown that pesticides are one of the top five environmental threats to children's health. The regulatory framework has not adequately considered the special vulnerability of children in its policy setting.

Relevance: Identifies a highly exposed, vulnerable population in specific locations. Focus on pesticides.

Support for existing criteria: Particular vulnerable population (farm children) with specific exposure (pesticides). Some of pesticides could be biomonitored.

17. Forging New Alliances: Building a Common Vision for California's Environment
Author: Latino Issues Forum
Date: April, 1999

Summary: In 1998, the Latino Issues Forum conducted a survey of registered Latino voters to look at how Latino voters feel about issues pertaining to the environment. Thirty percent of California's are Latino and they comprise 13 % of the electorate. In this survey, 620 registered Latino voters were surveyed. In a general survey on a variety of issues that preceded this specific environmental survey, Latino voters identified

environmental concerns as 2 of their top 5 concerns. When questioned further on environmental issues specifically 96% said that they believed preserving the environment was important. They perceived air quality in Sacramento and Central Valley as having gotten worse in the last 2 years. They perceived traffic as a problem and they believe that money should be spent on public transportation. They support more public participation in decision making and fell that they are not receiving adequate information about environmental threats.

Relevance: This survey provides information about Latino voters and their strong support for environmental issues as well as the need for better communication with them about the issues and their support for more participation in decision making.

Support for existing criteria: Focus on special ethnic population

Additions to existing criteria: none

18. PPIC Statewide Survey: Special Survey on Californians and the Environment
Author: Mark Baldassare; Public Policy Institute of California
Date: June 2002

Summary: The PPIC Statewide Survey is an ongoing series of public opinion polls designated to provide policymakers, the media and the general public with objective, advocacy-free information on the opinions and preferences of residents throughout California. This special edition presents the responses of 2,029adult residents throughout the state. Results show that there is pessimism about government's ability to handle environmental issues- almost one-half, 49%, say they have little or no confidence in government. Air pollution was ranked as a high concern (34%) with growth and development the next highest (13%). Most Californians view the pollution of water sources by urban and agricultural runoff (80%) and by toxic substances such as MTBE (74%) as at least somewhat of a problem. Traffic was a big concern in each region except the Central Valley. Of those surveyed, 58% said they believed that environmental injustices were a real and significant concern.

Relevance: Provides an additional indication of the concerns of Californians regarding environmental problems

Support for existing criteria: Environmental justice as a concern

Additions to existing criteria: add MTBE as a chemical of conc

Bibliography

1. "A Lifetime of Chemical Risk in the First Year," 2001.

2. Ashford, N., "Monitoring the Worker and the Community for Chemical Exposure and Disease: Legal and Ethical Considerations in the US," *Clinical Chemistry*, Vol. 40, No. 7, 1994.

3. Ashford, N., "The Importance of Public Participation in Contaminiated Communities," 2002.

4. Ashley, D.. Analytical Tecniques for Measuring Internal Dose Levels of Volatile Organic Compounds. 2002.
   Ref Type: Slide Presentation

5. Barr, D.. Biomonitoring of Exposure to Contrmporary Pesticides. 2002.
   Ref Type: Slide Presentation

6. Breast Cancer Action and The Breast Cancer Fund, "State of the Evidence: What is the Connection Between Chemicals and Breast Cancer?," 2002.

7. CAEPA, "Environmental Protection Indicators for California (The EPIC Report)," Oct. 2001.

8. CAEPA, "A Guide to Health Risk Assessment," 2002.

9. California Public Interest Research Group Charitable Trust, "Poisoning The Air: Airborne Pesticides in California," 1997.

10. CDC and ATSDR, "CDC and ATSDR's Proposed Plan for an Environmental Public Health Tracking Network," Aug. 2001.

11. CDC, "National Report on Human Exposure to Environmental Chemicals," Mar. 2001.

12. Clinton, H.. S.2054. S.2054. 3-21-2002.
    Ref Type: Bill/Resolution

13. Connick, S. and Innes, J., "Outcomes of Collaborative Water Policy Making: Applying Complexity Thinking to Evaluation," Mar. 1 A.D.

14. Council of State and Territorial Epidemiologists and National Institute of Occupational Health, "Indicators For Occupational Health Surveillance (Draft)," 2002.

15. De Rosa, C., Brown, D., Dhara, R., Garret, W., Hansen, H., Holler, J., and et al, "Dioxin and Dioxin-Like Compounds in Soil, Part 1:

ATSDR Interim Policy Guideline," *Toxicology and Industrial Health*, Vol. 13, No. 6, 1997, pp. 759-768.

16. Deck, W. and Kosatsky, T., "Communicating Their Individual Results to Participants in an Environmental Exposure Study: Insights from Clinical Ethics," *Env Research*, Vol. Section A80, 1999, pp. S223-S229.

17. Elemental Analysis Laboratory. Biomonitoring:Elemental Analysis, Heavy Metals and Beyond. 2002.
Ref Type: Slide Presentation

18. Environmental Health Investigations Branch and CADHS, "California Environmental Health Indicators," July 2002.

19. FDA, "Thimberosal in Vaccines," May 2002.

20. Foster and et al, "The Role of Community Review in Evaluation the Risks of Human Genetic Variation Research," *Am J.Human Genetics*, Vol. 64, 1999, pp. 1719-1727.

21. Goldman, L., Anton-Culver, H., Kharrazi, M., and Blake, E., "Banking of Human Tissue for Biomonitoring and Exposure Assessment: Utility for Environmental Epidemiology and Surveillance," *Environmental Health Perspectives*, Vol. 103, No. 3, 1995.

22. Greater Boston Physicians for Social Responsibility, "In Harm's Way: Toxic Threats to Child Development," 2000.

23. Gunter, E. W.. Biomonitoring Program. 2002.
Ref Type: Slide Presentation

24. Innes, J. and Greuber, J., "Planning Styles in Conflict at the San Francisco Bay Area's Metropolitan Transportation Commission," Sept. 2001.

25. Keeney, R. L., *Value-Focused Thinking: A Path to Creative Decisionmaking*, Harvard University Press, Cambridge, Massachusetts, 1992.

26. Kegly, S., Orme, S., and Neumeister, L., "Hooked on Poisin: Pesticide Use in Califronia, 1991-1998," 1999.

27. Kennedy, G. and Krivanek, N., "Some Thoughts About the Use and Communication of Toxicology Info," *Drug Metabolism Reviews*, Vol. 28, No. 1&2, 1996, pp. 235-243.

28. Koh, D. and Jeyaratnam, J., "Biomarkers, screening and ethics," *Ocupp Med*, 1998, pp. 48.

29. Latino Issues Forum, "Forging New Alliances: Building a Common Vision for California's Environment," Apr. 1999.

30. Latino Issues Forum, Environmental Health Program, Donoso, R., and Reyes, C., "Taking Action: Confronting the Health, Social and Environmental Factors Associated with Asthma in the Latino Community," Jan. 2002.

31. Malczewski, J., *GIS and Multicriteris Decision Analysis* 2002, pp. chapters 1 and 2.

32. Mark Baldassare and Public Policy Institute of California, "PPIC Statewide Survey: Special Survey on Californians and the Environment," June 2002.

33. National Bioethics Advisory Commision, "Ethical and Policy Issues in Research Involving Human Participants: Report and Recommendations of the National Biotethics Advisory Commision," *Ethical and Policy Issues in Research Involving Human Participants*, Vol. 1, 2001.

34. National Bioethics Advisory Commision, "Ethical and Policy Issues in Research Involving Human Participants: Summary," *Ethical and Policy Issues in Research Involving Human Participants*, 2001.

35. National Environmental Trust, "Toxic Beginings: A Lifetime of Chemical Exposure: In the First Year," 2001.

36. National Exposure Research Laboratory, National Center for Environmental Assessment, Office of Research and Development , and USEPA, "Strategic Plan for the Analysis of the National Human Exposure Assessment Survey (NHEXAS) Pilot Study Data," Nov. 2000.

37. Natural Resources Defense Council, "Trouble on the Farm: Growing Up With Pesticides in Agricultural Communities," Oct. 1998.

38. Needham, L.. Biomonitoring Workshop Presentation. 2002.
Ref Type: Slide Presentation

39. Office of Environmental Health hazard Assessment and CAEPA, "California Comparative Risk Project Summary Report," 1994.

40. Office of Prevention and Toxics and USEPA, "
Methodology for Selecting Chemicals for the Voluntary Children's Chemical Evaluation
Program (VCCEP) Pilot," Dec. 2000.

41. Pacific Institute for Studies in Development, E. a. S., "Neighborhood Knowledge For A Change: The West Oakland Environmental Indicators Report," Jan. 2002.

42. Pastor, C., DHHS, CDC, and National Center for Health Statistics, "Attention Deficit Disorder and Learning Disability: United States 1997-98," *Vital and Health Statistics*, Vol. 10, No. 206, 2002.

43. Patterson, D. and CDC. Biomonitoring for Persistant Organic Pollutants. 2002. Ref Type: Slide Presentation

44. Perry, S. and Thamer, M., "Medical Innovation and the Critical Role of Health Technology Assessment," *JAMA*, Vol. 282, No. 19, 1999.

45. Pesticide Action Network, "Hooked on Poison: Pesticide Use in California 1991-1998," 1999.

46. Physicians For Social Responsibility and The California Public Interest Research Group Charitable Trust, "Generations At Risk: How Environmental Toxicants May Affect Reproductive Health In California (Executive Summary)," 1995.

47. Rothstein, M., "Ethical Guidelines for Medical Research on Workers," *J Occup Env Med.*, Vol. 42, 2000.

48. Ryan, D. and et al, "The Promise of Environmental Sampling and Right-to-Know Laws for At-Risk Communities," *Public Health Reports*, 2000, pp. 115.

49. Samson, E. and et al, "Technical and Scientific Developments in Exposure Marker Methodology," *Clinical Chemistry* , Vol. 40, No. 7, 1994, pp. 1376-1384.

50. Soskolne, C., "Ethical, Social, and Legal Issues Surrounding Studies of Susceptible Populations and Individuals," *Env Health Perspective*, Vol. 105, No. 4, 1997.

51. The Environmental Health Tracking Project Team of The Pew Environmental Health Commission at the Johns Hopkins School of Hygiene and Public Health., "America's Environmental Health Gap: Why the Country Needs A Nationwide Health Tracking Network," Sept. 2002.

52. Trust for America's Health and Locke, P., "Birth Defects Tracking and Prevention: Too Many States Are Not Making the Grade," 2002.

53. United States General Accounting Office, "Toxic Chemicals: Long Term Coordinated Strategy Needed To Measure Exposures in Humans," May 2002.

54. USGS, "Pharmaceuticals, Hormones and Other Organic Wastewater Contaminants in U.S. Streams," USGS Fact Sheet FS-027-02, Mar. 2002.

55. Weiss, B., "Ethics Assessment as an Adjunct to Risk Assessment in the Eval of Developmental Neurotoxicants," *Env Health Perspectives*, 2001.

56. Wiedemann, P. and Schutz H, "Risk Communication for Environmental Health Hazards," *Zbl Hug.Umweltmed*, Vol. 202, 1998